ID-NET™ USER MANUAL

19 August 2009
Version 1.0

NOVARTIS–CIRG

STUDY TRIO-CIRG 019/ CRAD001 J2301 (BOLERO-1)

A Randomized Phase III, Double-Blind, Placebo-Controlled Multicenter Trial of Everolimus in Combination with Trastuzumab and Paclitaxel, as First Line Therapy in Women with HER2 Positive Locally Advanced or Metastatic Breast Cancer

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1 Introduction

This document describes the features and use of ID-net™, the IDDI IWRS system, for the BOLERO-1 study. The features included are those available for the following user profiles (user types): Investigator, Study Coordinator, Pharmacist, Monitor, Sponsor, CIRG Officer, Safety Officer, and Drug Distributor.

1.1 User Profiles

The ID-net transactions available for each user profile are as follows:

1.1.1 Investigator

- Subject Registration
- Subject Screen Failure
- Medication Allocation
- End of Randomized Treatment
- Code Break
- Confirm Receipt of Medication
- Report Damaged Medication
- View Subject information

1.1.2 Study Coordinator

- Subject Registration
- Subject Screen Failure
- Medication Allocation
- End of Randomized Treatment
- Confirm Receipt of Medication
- Report Damaged Medication
- View Subject information

1.1.3 Pharmacist

- Medication Allocation
- End of Randomized Treatment
- View Subject information

1.1.4 Sponsor (CIRG & Novartis)

- View Subject information
- Site Activation
- Access online reports

1.1.5 CIRG Officer

- Subject Randomization
- Subject Screen Failure
- Site Activation
- Access online reports

1.1.6 Monitor

- View Subject information
- Access online reports

1.1.7 Safety Officer

- View Subject information
- Code Break
- Access online reports

1.1.8 Drug Distributor (supplier)

- Confirm dispatch of orders
- Confirm receipt of kits by the depot
- Access online reports

1.2 Study Design

This is a randomized phase III, double-blind, placebo-controlled multicenter study of Everolimus in combination with Trastuzumab and Paclitaxel, as first-line therapy for women with HER2-positive, locally advanced or metastatic breast cancer. The study will include 717 subjects at ~250 study sites worldwide.

The stratification criteria are:

- Visceral (lung, liver, peritoneal or pleural) Metastasis (Yes *vs.* No)
- Prior adjuvant or neo-adjuvant treatment with trastuzumab (Yes *vs.* No)

To register a subject in the study, you will need the following information:

- Subject's date of birth (dd/mmm/yyyy)
- Your ID-net login and password

1.3 Web Browser Requirements

ID-net requires Microsoft Internet Explorer® (IE) ver. 5.5 or higher, running on Windows 98® or newer. For best performance, use IE 6 or IE 7 on Windows XP® or newer. *We do not recommend using Internet Explorer 8 at this time.*

Firefox, Netscape, Opera, Safari, and other Web browsers are not supported and will not work properly with ID-net. Mac OS, Linux, Solaris, and other UNIX and UNIX-derived operating systems are not supported.

2 ID-net™

2.1 Logging onto ID-net™

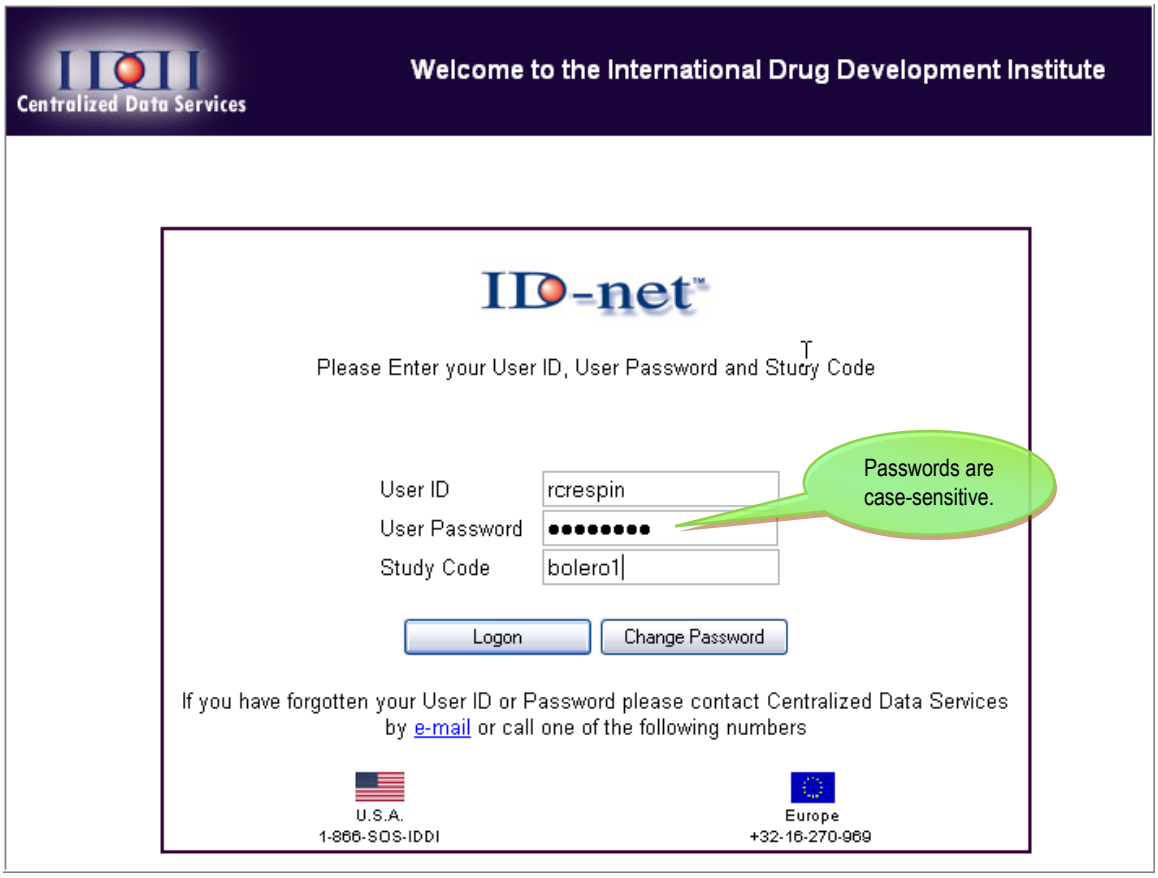
ID-net™ is a Web-based software application connected to a centralized database. It is used for managing subject registration, randomization, and treatment; for data collection; and for managing medication supplies. Users access ID-net *via* the Internet using Microsoft Internet Explorer® (other Web browsers are not supported). The address (URL) for the secure ID-net Web site is **https://idnet.iddi.com**

This is the URL for ID-net.

A User ID and password are required to log onto ID-net. These will be provided to you by your monitor at an appropriate time. User IDs and passwords must not be shared. Additional site-users can be added at any time if needed.

You will also need a Study Code to log onto ID-net. The Study Code for this study is **bolero1**.

The ID-net Logon screen.



Log onto ID-net by entering your User ID, password (case-sensitive), and the Study Code into the appropriate fields on the Logon screen and clicking the Logon button. The first time you log onto ID-net and every 90 days thereafter, you will be required to change your password. You may also change your password at any time from the Logon screen by entering your logon information and clicking the Change Password button.

The Change Password dialogue.

2.2 Passwords

Important! Passwords are case-sensitive (PASSWORD is different from password).

Repeated attempts to log onto ID-net with an incorrect password will result in your account being locked. If you forget your password, please contact the Help Desk to have it reset.

There are no specific requirements for creating passwords; however, we recommend you choose a password containing at least eight characters for security reasons.

3 ID-net Home Page

Logging onto ID-net brings you to your Home Page. From here you can access every ID-net function available to you. The Home Page screen consists of three parts:

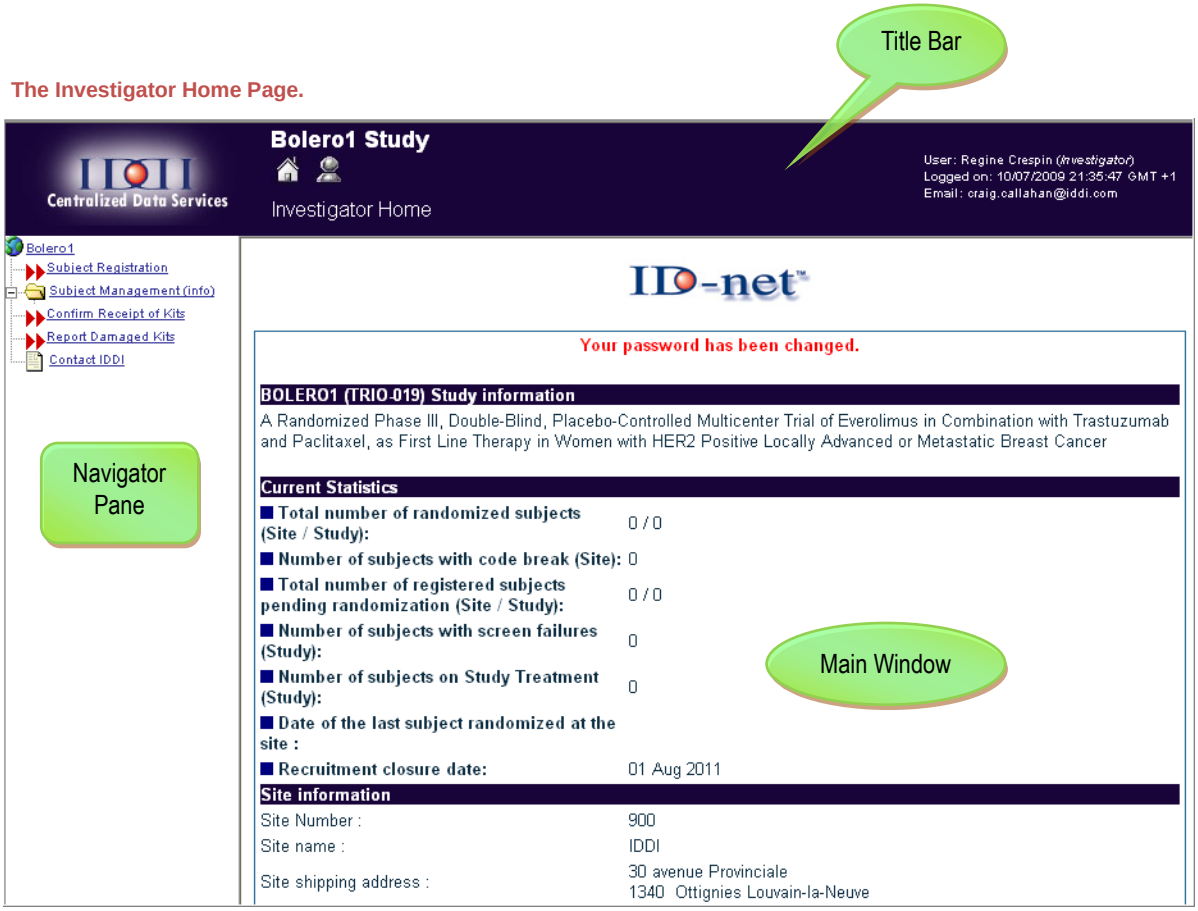
- **Title Bar:** Displayed here is the study name, your name and email address, the time and date you logged on, and the *Exit to Portal* button.

Click this icon to log off ID-net:

- **Main Window:** Displayed here is information about the study and your site. This is also where the Registration and other data-capture screens and information screens will appear as you perform tasks in ID-net.

- **Navigator Pane ("tree view"):** Here you find links for the various actions you can perform, subject information, and IDDI contact information.

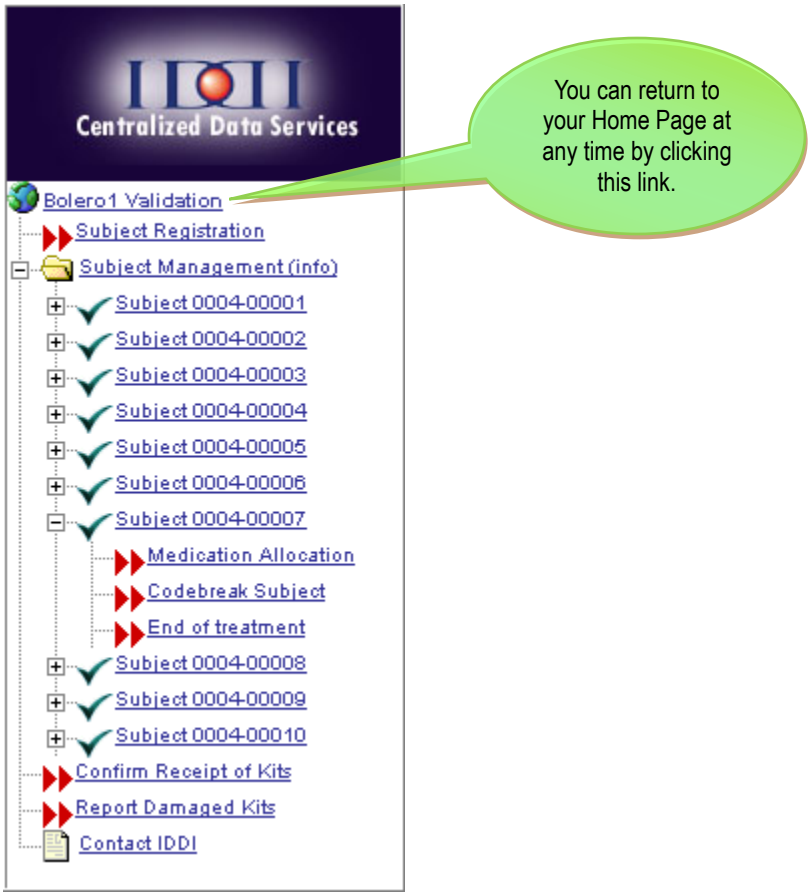
The Investigator Home Page.



3.1 Navigator Pane

The Navigator pane (“tree view”) is where you access subject information and the various actions available to you. The items in this pane are hyperlinks which you click to access information or a function.

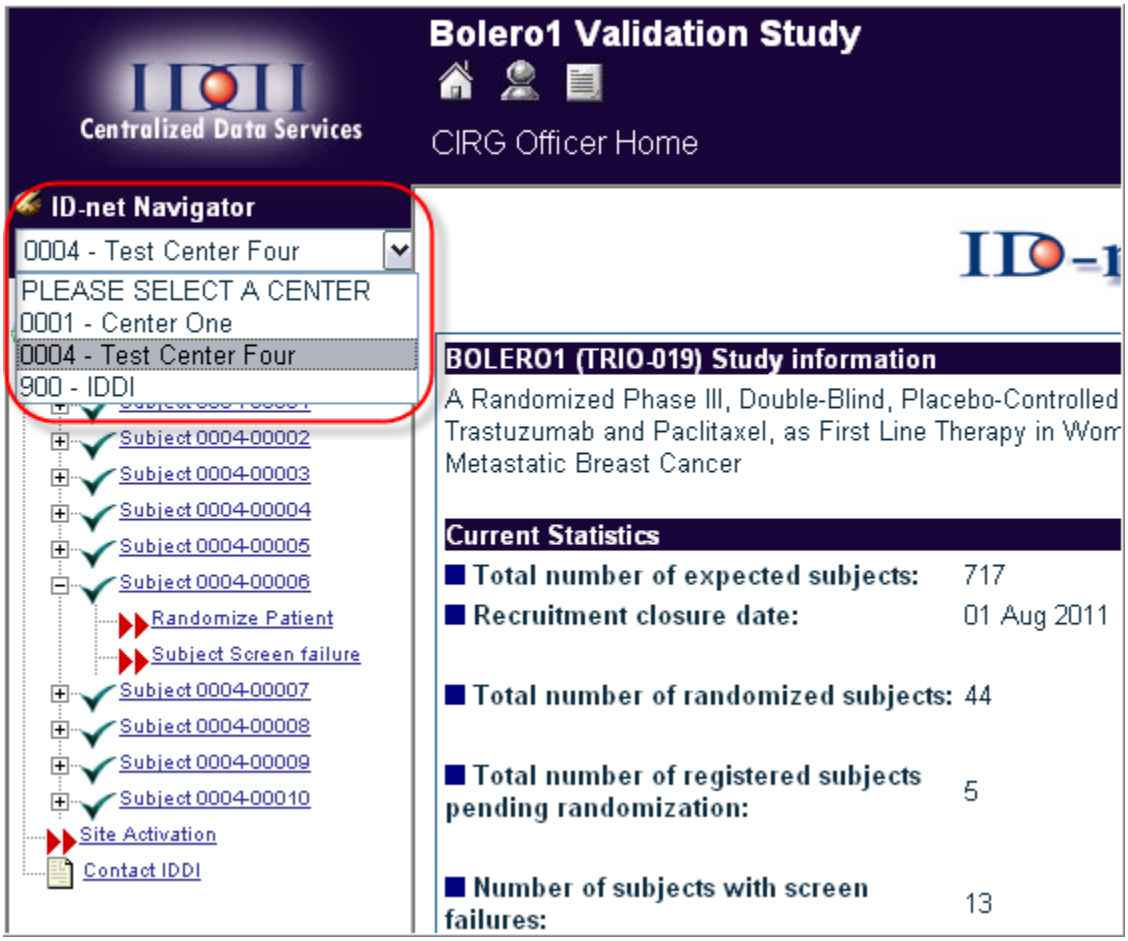
Investigator Navigator Pane (“tree view”)



Transactions related to subjects are accessed by clicking on the ‘+’ symbol in the small box next to the subject’s Subject ID. Only those transactions available for your specific profile will be visible. If the subject options are already displayed, the symbol in the box is the ‘-‘ sign; clicking on this will collapse the options tree for that subject.

The subjects registered at the site are automatically displayed for site-level users. Monitors, Sponsors, CIRG Officers, and Safety Officers need to choose a site from a drop-down list to see the subjects at that site and access the available transactions for those subjects.

CIRG Officer Navigator pane. Choose a site from the drop-down list to see the subjects at that site.



3.2 Navigator Options

Investigators and Study Coordinators

- Subject Registration
- View subject information (by clicking on the Subject ID)
- View a table of all subjects in the study ("Subject Management (info)")
- Confirm Receipt of Kits
- Report Damaged Kits
- IDDI contact information

Pharmacists

- Confirm Receipt of Kits
- Report Damaged Kits
- View subject information (by clicking on the Subject ID)
- View a table of all subjects in the study ("Subject Management (info)")
- IDDI contact information

Monitors, Safety Officers

- View subject information ("Subject Details")
- View a table of all subjects in the study ("Subject Management (info)")
- Access the online reports (click the *Online Reports* icon)
- IDDI contact information

CIRG Officers, Sponsors

- View subject information ("Subject Details")
- View a table of all subjects in the study ("Subject Management (info)")
- Access the online reports (click the *Online Reports* icon)
- Site Activation
- IDDI contact information

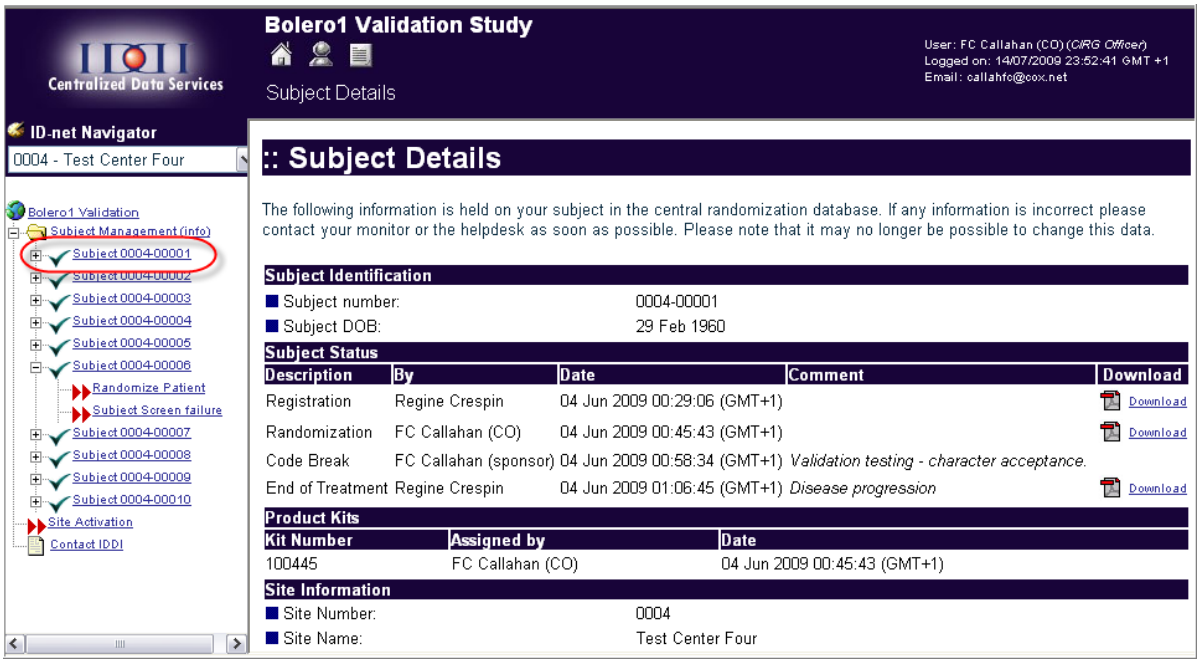
Drug Distributors

- Confirm dispatch of orders
- Confirm receipt of kits (at the depot)
- Access the online reports (click the *Online Reports* icon)
- IDDI contact information

4 Subject Details

Clicking directly on a Subject ID will display the *Subject Details* screen for that subject. Clicking a *Download* link on the right side of the window will open the associated confirmation document for that transaction in PDF format. The document may be printed or saved to your hard drive.

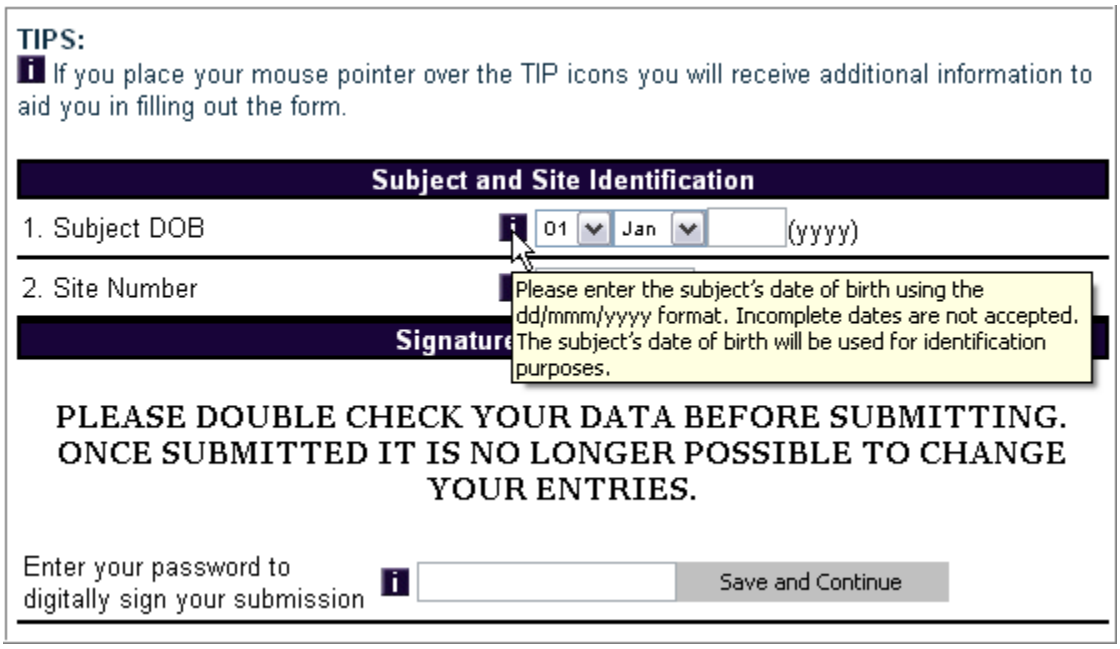
The Subject Details screen.



5 TIPS

Most screens in ID-net that allow the entry of data by the user include pop-up tips to aid in the accurate entry of the information. To view the tip for a data field, hover the mouse pointer over the associated i icon.

Hold the pointer of your mouse over a TIP icon to see the pop-up tip.

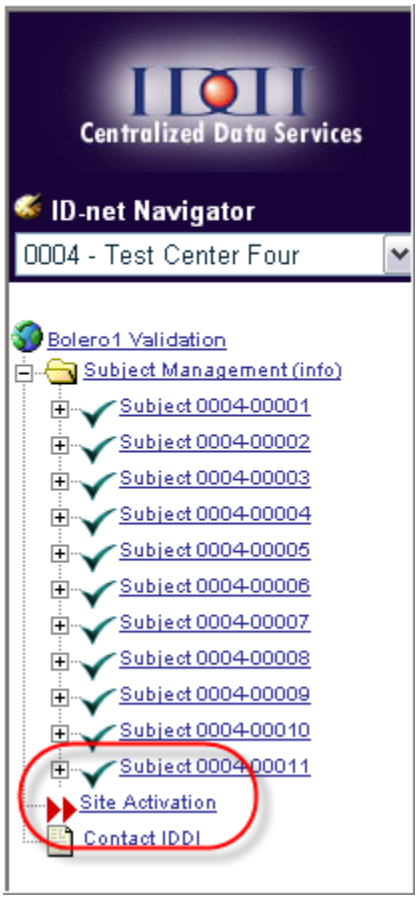


6 Site Activation (Sponsor and CIRG Officer)

Before a site can register subjects or receive medication supply shipments, the site must first be activated in ID-net. This feature is reserved for users with the CIRG Officer profile.

To activate a site, log into ID-net and click the *Site Activation* link in the tree view. This opens the activation screen.

Click the Site Activation link to access the activation screen.



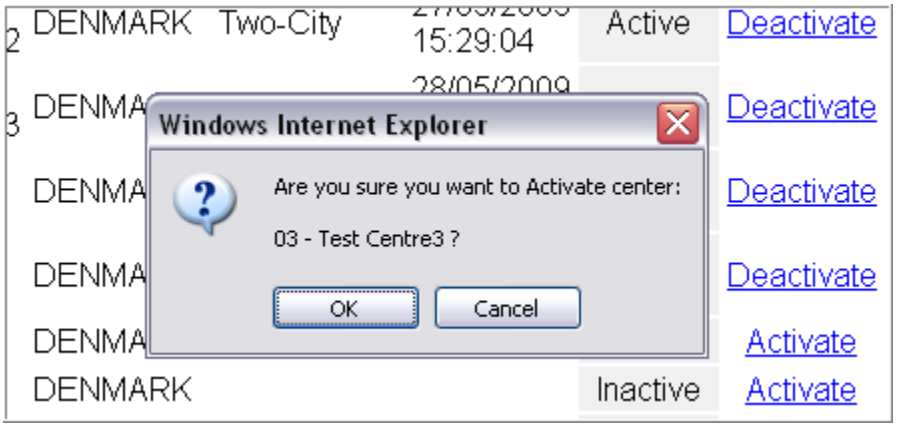
Scroll through the list to find the site you wish to activate (sites are listed in numerical order). When you find the site, click the *Activate* link in the far-right column ("Action"). A pop-up window will appear, asking if you wish to activate the site.

Click the *Activate* link to activate Site 03.

Site Activation

Site Number	PI Name	Country	City	Activation date	Current activation status	Action
0001	I Nvestigator1	DENMARK	One-City	27/05/2009 15:29:02	Active	Deactivate
0002	I Nvestigator2	DENMARK	Two-City	27/05/2009 15:29:04	Active	Deactivate
0003	I Nvestigator3	DENMARK	Three-City	28/05/2009 16:44:31	Active	Deactivate
0004	Mr Arnaud Invest	DENMARK	Testberg	28/05/2009 16:44:33	Active	Deactivate
01		DENMARK	DK- 8000 Arhus C	14/05/2009 16:38:56	Active	Deactivate
02		DENMARK	Copenhagen		Inactive	Activate
03		DENMARK			Inactive	Activate
04		DENMARK			Inactive	Activate
900	Jerome Investigator	BELGIUM	Ottignies Louvain-la-Neuve	08/06/2009 17:07:40	Active	Deactivate

Click the *OK* button to confirm the activation.



The activation screen updates to indicate the activation was successful. The *Activate* link changes to *Deactivate* for activated sites. To deactivate a site, follow this same procedure, only clicking the *Deactivate* link.

Site 03 has been activated.

02	DENMARK Copenhagen		Inactive	Activate
03	**DENMARK**	**14/08/2009 00:17:34**	**Active**	Deactivate
04	DENMARK		Inactive	Activate

7 Registration

A subject must be registered in ID-net in order to participate in the study. Subjects must sign informed consent prior to being registered.

- All individuals who sign informed consent should be registered in the study.

To register a subject you will need the Subject's date of birth. Subjects must be 18 years of age or older.

7.1 Registering a New Subject

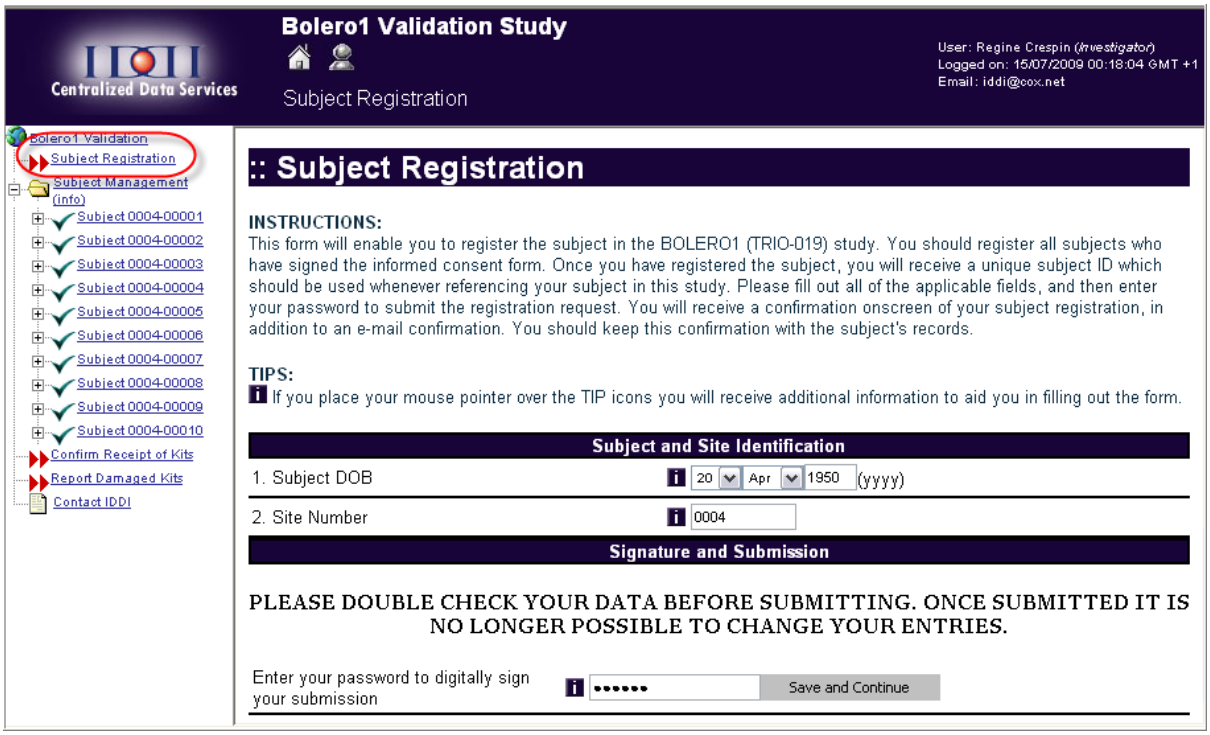
To register a new subject, click the *Subject Registration* link in the tree view. This opens the Registration data-capture screen.

Enter the subject's date of birth in the appropriate fields, and sign the form using your ID-net password. Your site number will be pre-filled on the form; if this number is not correct, do not continue with the registration, and contact your monitor or the IDDI Help Desk.

- If the date of birth for your subject is the same as the date of birth of another subject already registered at your site, you will receive a notification message in order to confirm you have entered the information correctly. You may continue with the registration if you are registering a new subject and the date of birth is correct, or you may cancel the registration if the subject has already been registered.

You will see this message if the DOB of your new subject is the same as the DOB of a subject already registered at your site.

The Registration form with all fields completed.

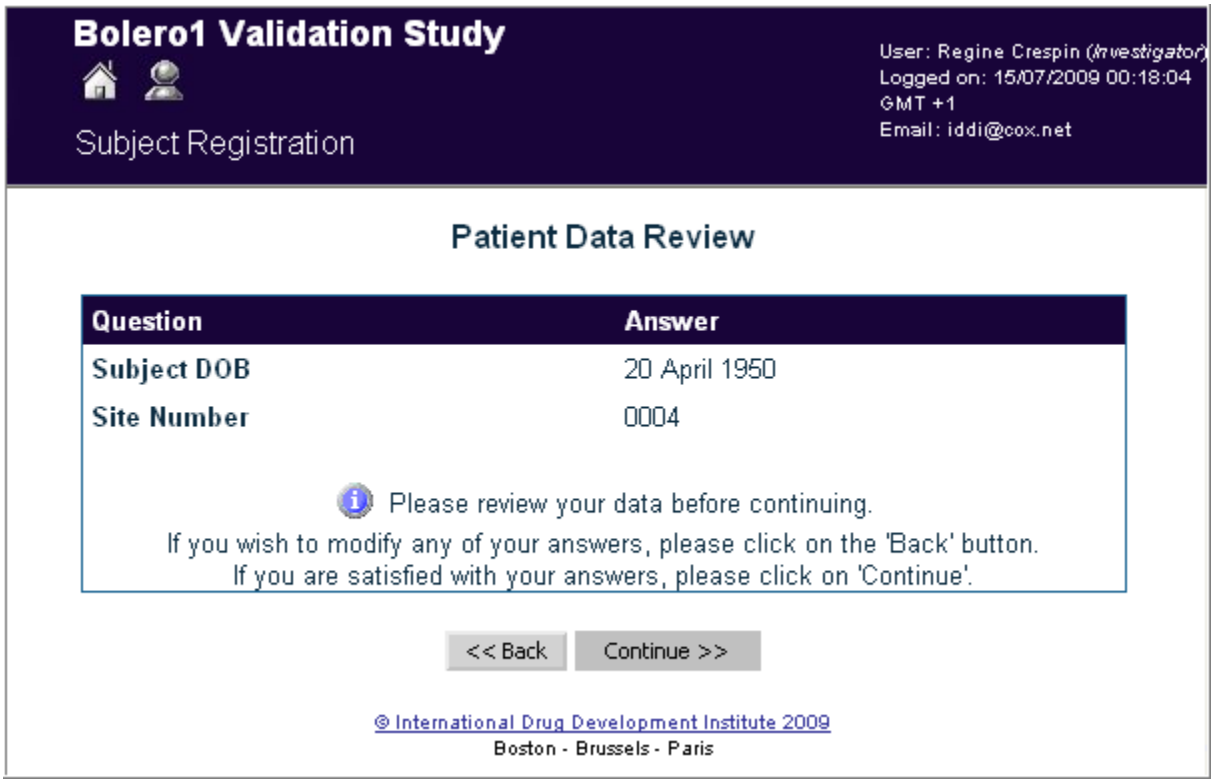


Signing the Registration form.

7.2 Registration Data Review

When you click the *Save and Continue* button on the Registration form, you will be presented with the Data Review screen. Here you may review the information entered for your subject. If the date of birth is incorrect or you have previously registered the subject, click the *Back* button to return to the Registration form. If the DOB is correct, click the *Continue* button to complete the registration.

Registration Data Review screen.



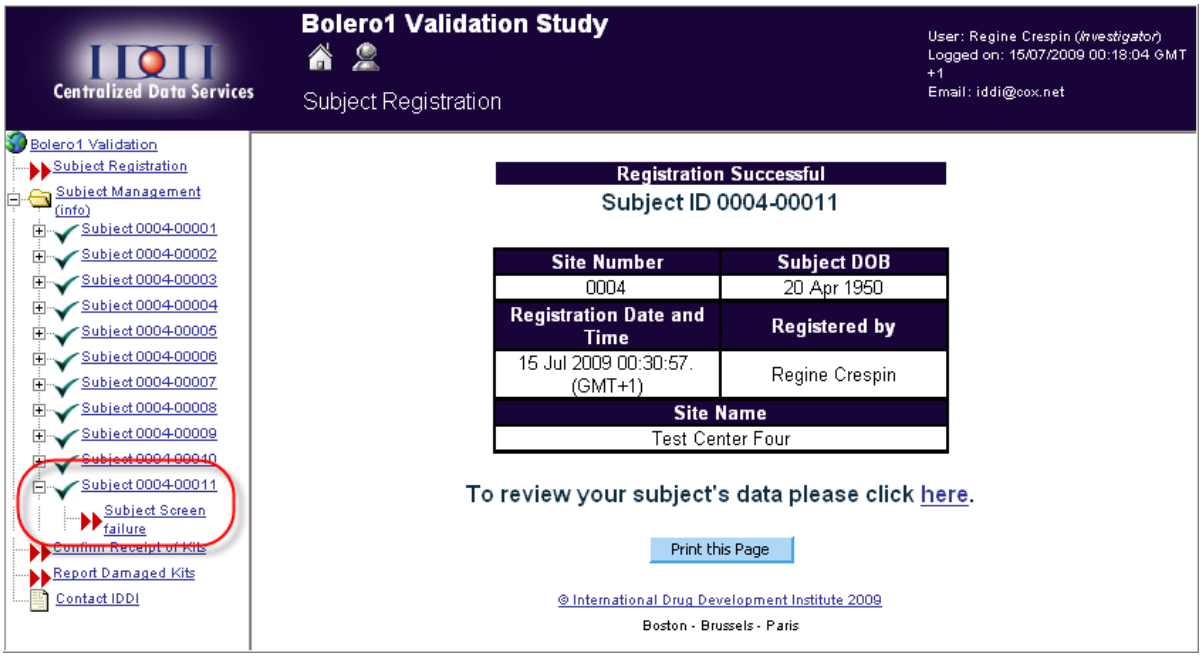
7.3 Registration Result Screen

When you click the *Continue* button on the Data Review screen, the transaction is completed and you are presented with the Registration Result screen. On this screen you will see the subject's Subject ID, the date and time of the registration, and other relevant information. Note that all dates and times in ID-net are the local time in Belgium, where the IDDI servers are located. Your new subject will now also appear in the list of subjects in the tree view.

- The **Subject ID** is in the format *XXXX-XXXXX*, and consists of the four-digit site number, a dash, and a five-digit number sequential at the site level.

You may print the Result screen for your records by clicking the *Print This Page* button. Please note that once you leave this screen, it is no longer available for viewing or printing.
All designated users will receive a confirmation document in PDF format as an email attachment.

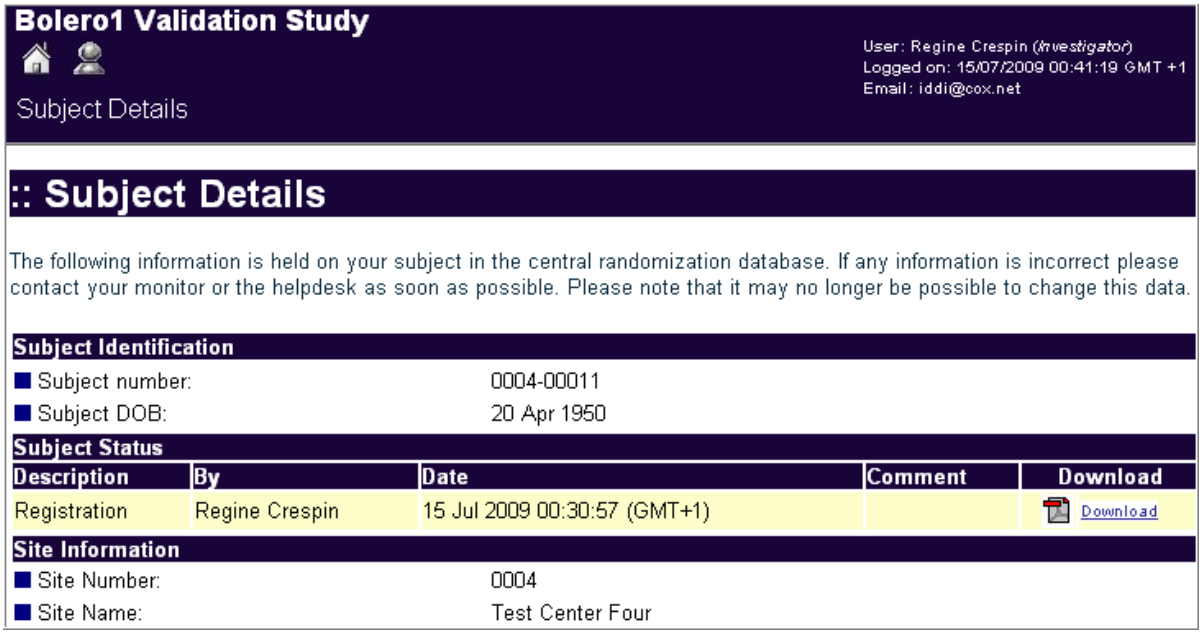
The Registration Result screen.



7.4 Subject Details

The details of the registration are presented on the subject's Subject Details screen. You may also view, print, or download the registration confirmation document in PDF format by clicking the associated *Download* link.

Subject Details after Registration.



IMPORTANT: Upon registration of the patient in ID-net, the 5 RANDOMIZATION FORMS pages must be completed and sent to CIRG for randomization of the subject in the study:

For Australia, Canada, USA and LatAm countries:	**For all other countries:**
Fax: + 1.780.702.0189	Fax: + 33.1.58.10.09.10

Or send them by email to: rando019@cirg.org

CIRG will contact you in case a clarification is required or in case the subject is determined to be ineligible. If the subject is determined to be eligible, she will be promptly randomized by CIRG and you will automatically receive a confirmation document in PDF format as an email attachment.

8 Screen Failure

If a registered subject is determined to be ineligible prior to being randomized in the study, you should report the subject as a screen failure in ID-net.

- Please note: Once a subject is randomized, the Screen Failure option is no longer available.

8.1 Completing the Screen Failure Form

To record a subject as a screen failure, open the options for the subject in the tree view by clicking the '+' symbol next to the Subject ID, and then click the *Subject Screen Failure* link. This opens the Screen Failure data-capture screen.

Complete the form, entering the requested information in each section.

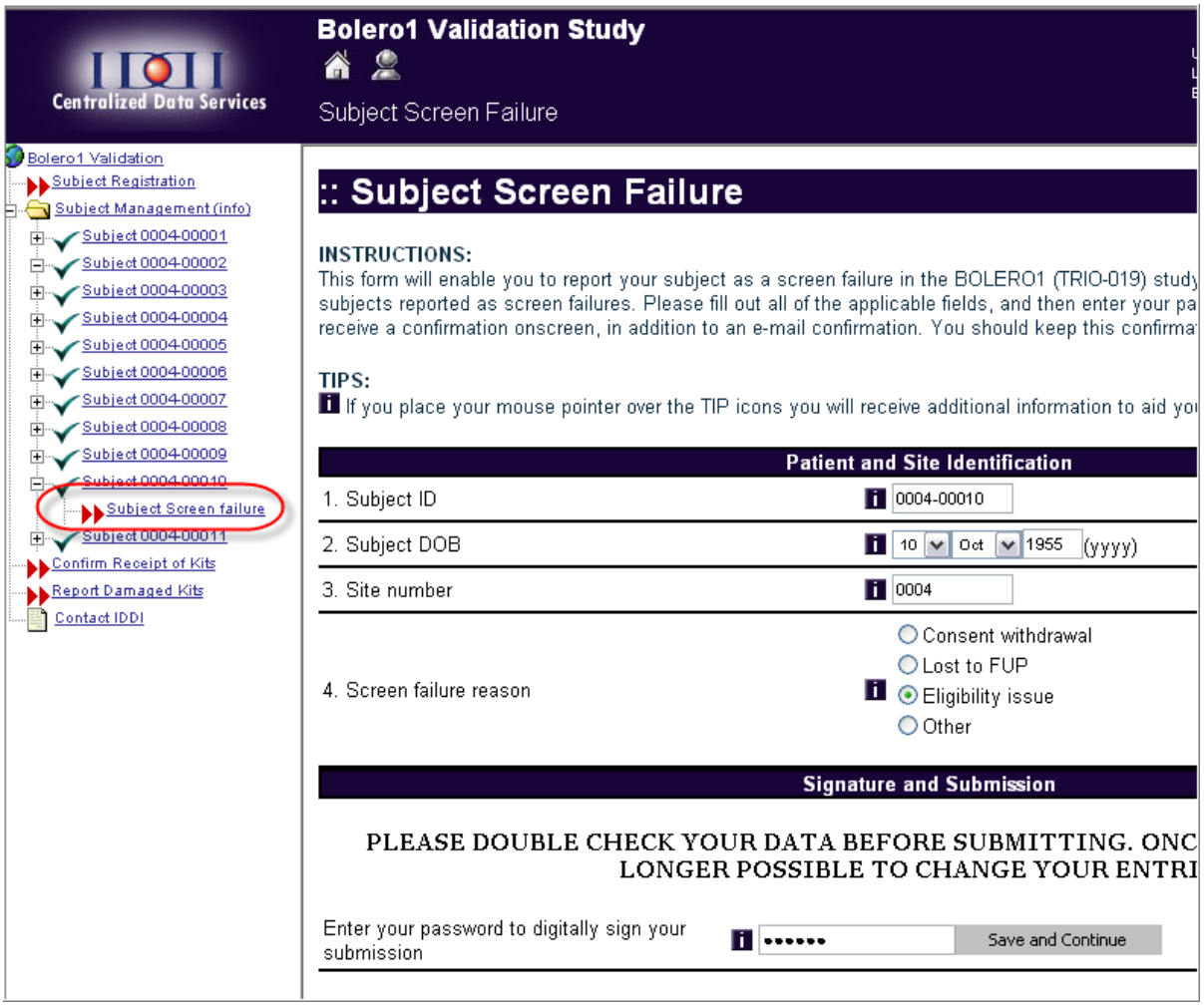
- **Subject ID:** pre-filled
- **Subject DOB:** Enter the date of birth recorded at the time of registration.
- **Site Number:** This is pre-filled. If the site number is incorrect, cancel the screen failure and contact your monitor or the IDDI Help Desk.
- **Screen Failure Reason:** Choose one of the four available reasons for screen failure:
  - Consent Withdrawal
  - Lost to FUP
  - Eligibility Issue
  - Other

You must choose a reason for screen failure to complete the transaction.

Sign the form with your ID-net password and click the *Save and Continue* button. This will take you to the Screen Failure Data Review screen.

Signing the Screen Failure form.

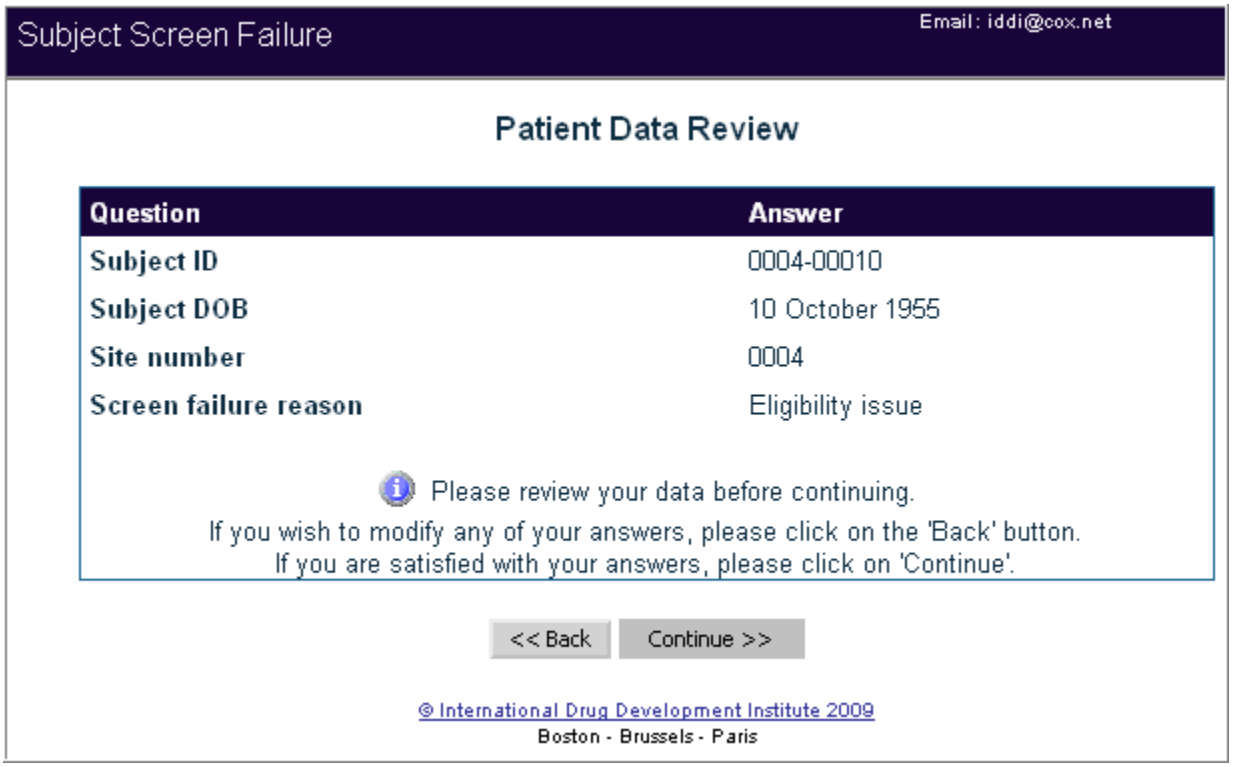
The Screen Failure form with all fields completed.



8.2 Screen Failure Data Review

When you click the *Save and Continue* button on the Screen Failure form, you will be presented with the Data Review screen. Here you may review the information entered for your subject. If any of the information is incorrect, click the *Back* button to return to the Screen Failure form. If all information is correct, click the *Continue* button to complete the screen failure transaction.

The Screen Failure Data Review screen.



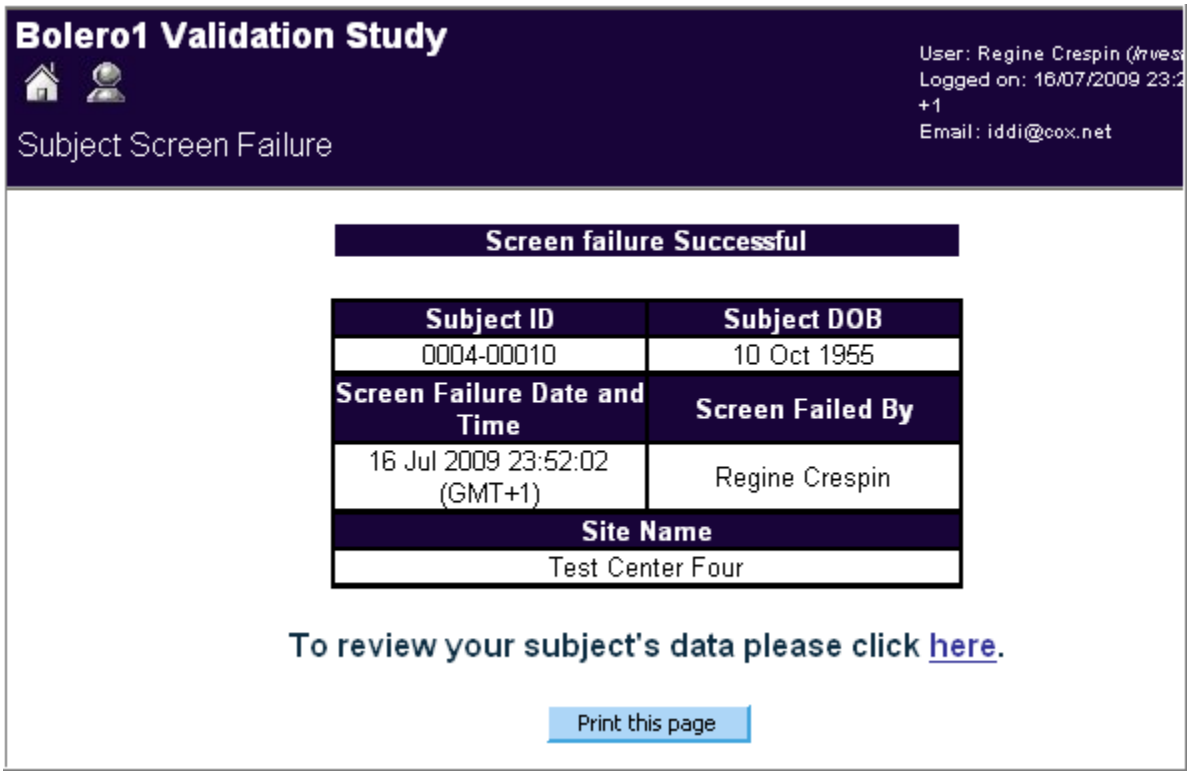
8.3 Screen Failure Result Screen

When you click the *Continue* button on the Data Review screen, the transaction is completed and you are presented with the Screen Failure Result screen. On this screen you will see various information related to the screen failure, including the date and time of the screen failure, the individual who performed the screen failure, and other relevant information. Note that all dates and times in ID-net are the local time in Belgium, where the IDDI servers are located.

You may print the Result screen for your records by clicking the *Print This Page* button. Please note that once you leave this screen, it is no longer available for viewing or printing. All designated users will receive a confirmation document in PDF format as an email attachment.

- No further actions are available for subjects reported as screen failure.

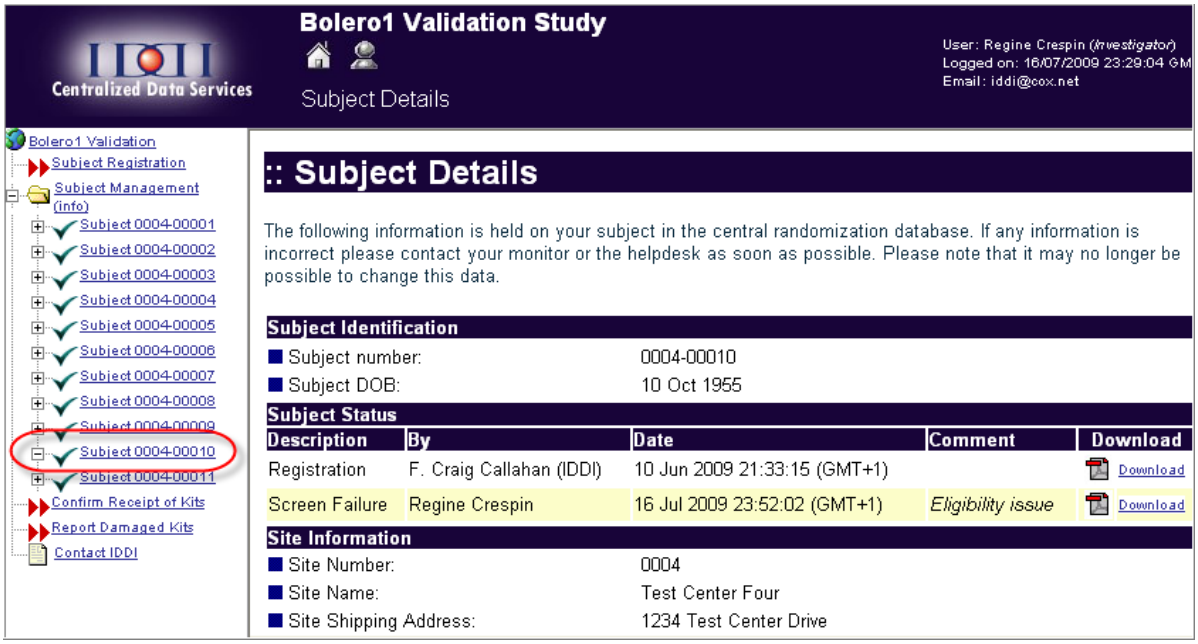
The Screen Failure Result screen.



8.4 Subject Details

The details of the screen failure are presented on the subject's Subject Details screen. You may also view, print, or download the screen failure confirmation document in PDF format by clicking the associated *Download* link.

Subject Details following Screen Failure. Note that no further actions are available for this subject.



9 Randomization (CIRG Officer)

Registered subjects who meet all eligibility criteria may be randomized. Only users with the CIRG Officer profile may randomize subjects.

9.1 Requirements for Randomization

In order to randomize a subject, the CIRG Officer will need to know whether the subject has visceral metastases, and if the subject has had prior adjuvant treatment with trastuzumab. CIRG will also have to confirm that all inclusion/exclusion criteria have been met. In addition, the site will need to have "On Site" at least one blinded medication kit for each treatment arm (RAD001 and Placebo).

- Randomization will not be possible if the site does not have sufficient study drug on site and confirmed in the ID-Net system.

9.2 Completing the Randomization Form

To randomize a subject, select the subject's site from the drop-down list. Open the options for the subject in the tree view by clicking the '+' symbol next to the Subject ID, and then click the *Randomize Subject* link. This opens the Randomization data-capture screen.

Complete the form, entering the requested information in each section.

All questions must be answered to complete the randomization.

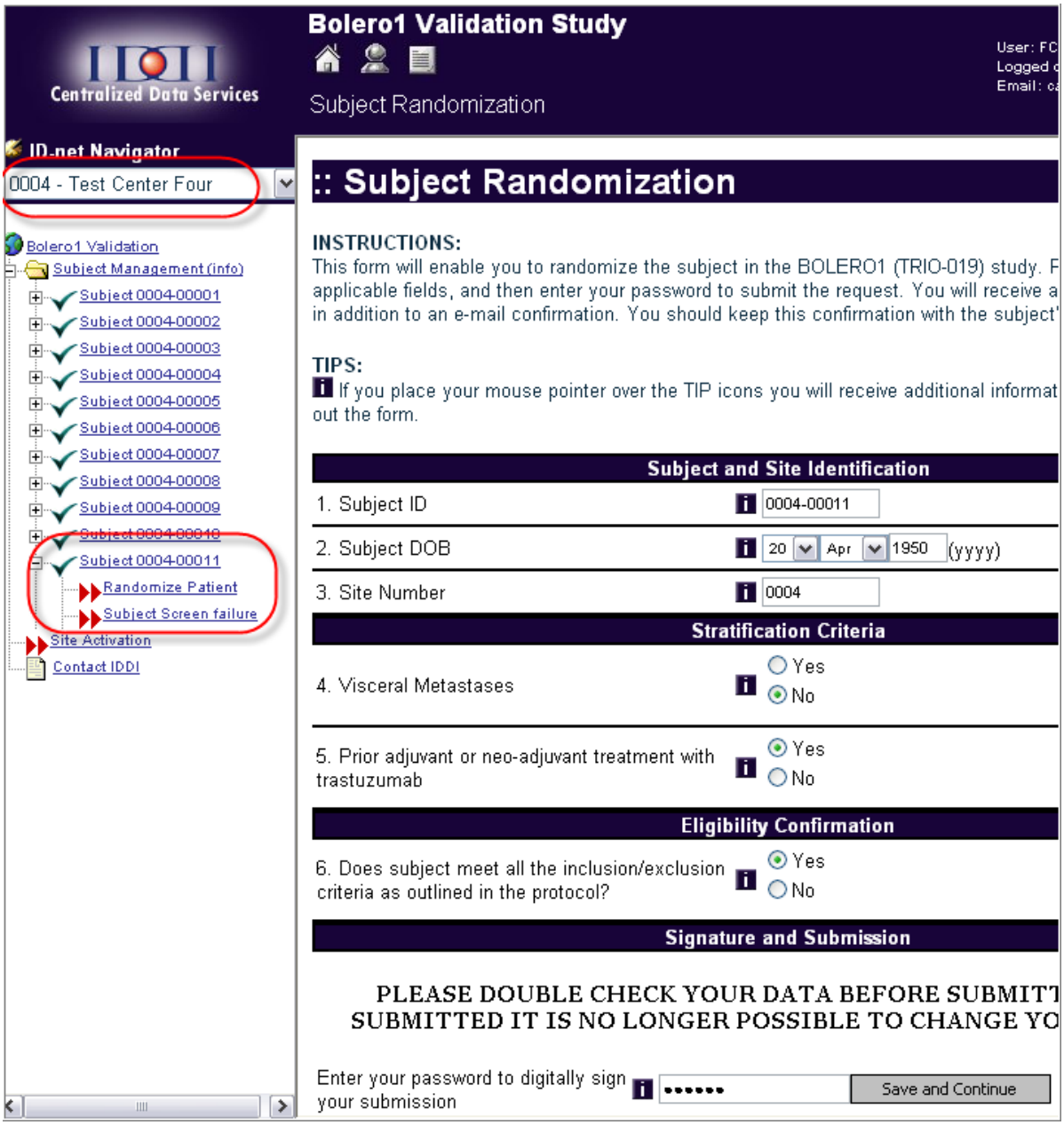
- **Subject ID:** pre-filled
- **Subject DOB:** Enter the date of birth recorded at the time of registration.
- **Site Number:** This is pre-filled. If the site number is incorrect, cancel the randomization and contact the IDDI Help Desk.
- **Stratification Criteria:**
  - Visceral Metastases (Yes/No)
  - Prior adjuvant treatment with trastuzumab (Yes/No)
- **Eligibility Confirmation:**
  - Does the subject meet all the inclusion/exclusion criteria as outlined in the protocol? (Yes/No)
  - *If the answer to this question is 'No', the subject will not be randomized. Please record the subject as a screen failure (Section 5 above).*

The subject cannot be randomized if the answer to the Eligibility Confirmation question is "No".

Sign the form with your ID-net password and click the *Save and Continue* button. This will take you to the Randomization Data Review screen.

Signing the Randomization form.

The Randomization form with all fields completed.



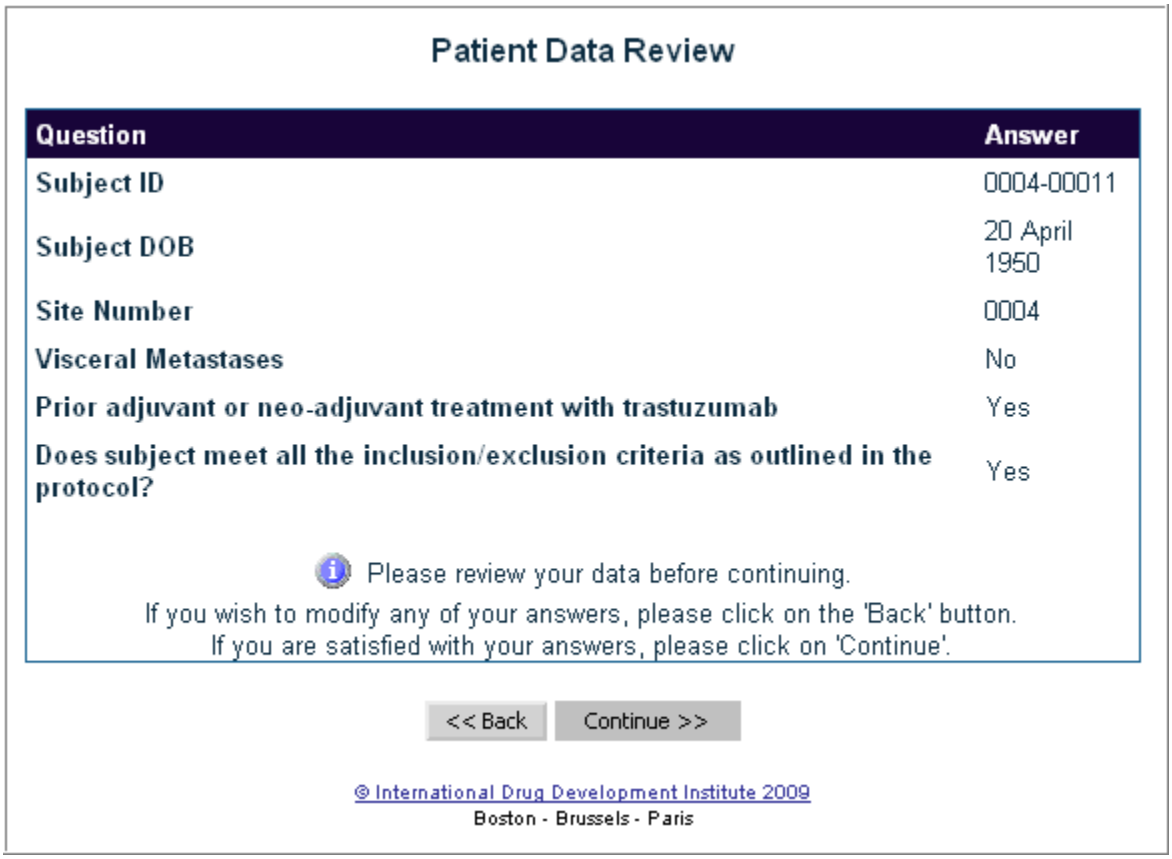
9.3 Randomization Data Review

When you click the *Save and Continue* button on the Randomization form, you will be presented with the Data Review screen. Here you may review the information entered for your subject. If any of the information is incorrect, click the *Back* button to return to the Randomization form.

- **Please review this information carefully! Once the subject is randomized, it may not be possible to correct any errors.**

If all information is correct, click the *Continue* button to complete the randomization.

The Randomization Data Review screen.



9.4 Randomization Result Screen

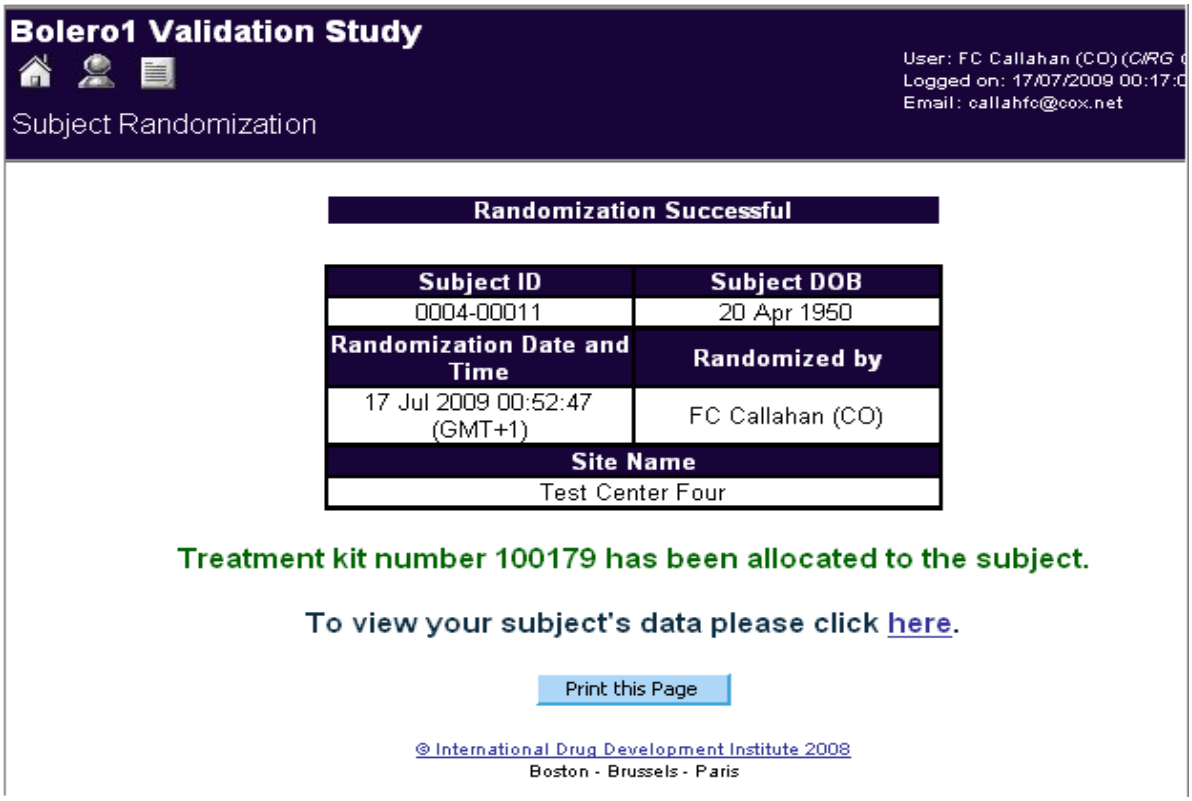
When you click the *Continue* button on the Data Review screen, the transaction is completed and you are presented with the Randomization Result screen. On this screen you will see information related to the randomization, including the medication kit allocated to the subject, the date and time of the randomization, the individual who performed the randomization, and other relevant information. Note that all dates and times in ID-net are the local time in Belgium, where the IDDI servers are located.

You may print the Result screen for your records by clicking the *Print This Page* button. Please note that once you leave this screen, it is no longer available for viewing or printing. All designated users will receive a confirmation document in PDF format as an email attachment.

The following actions are available for the subject after randomization:

- Medication Allocation
- Code Break
- End of Treatment

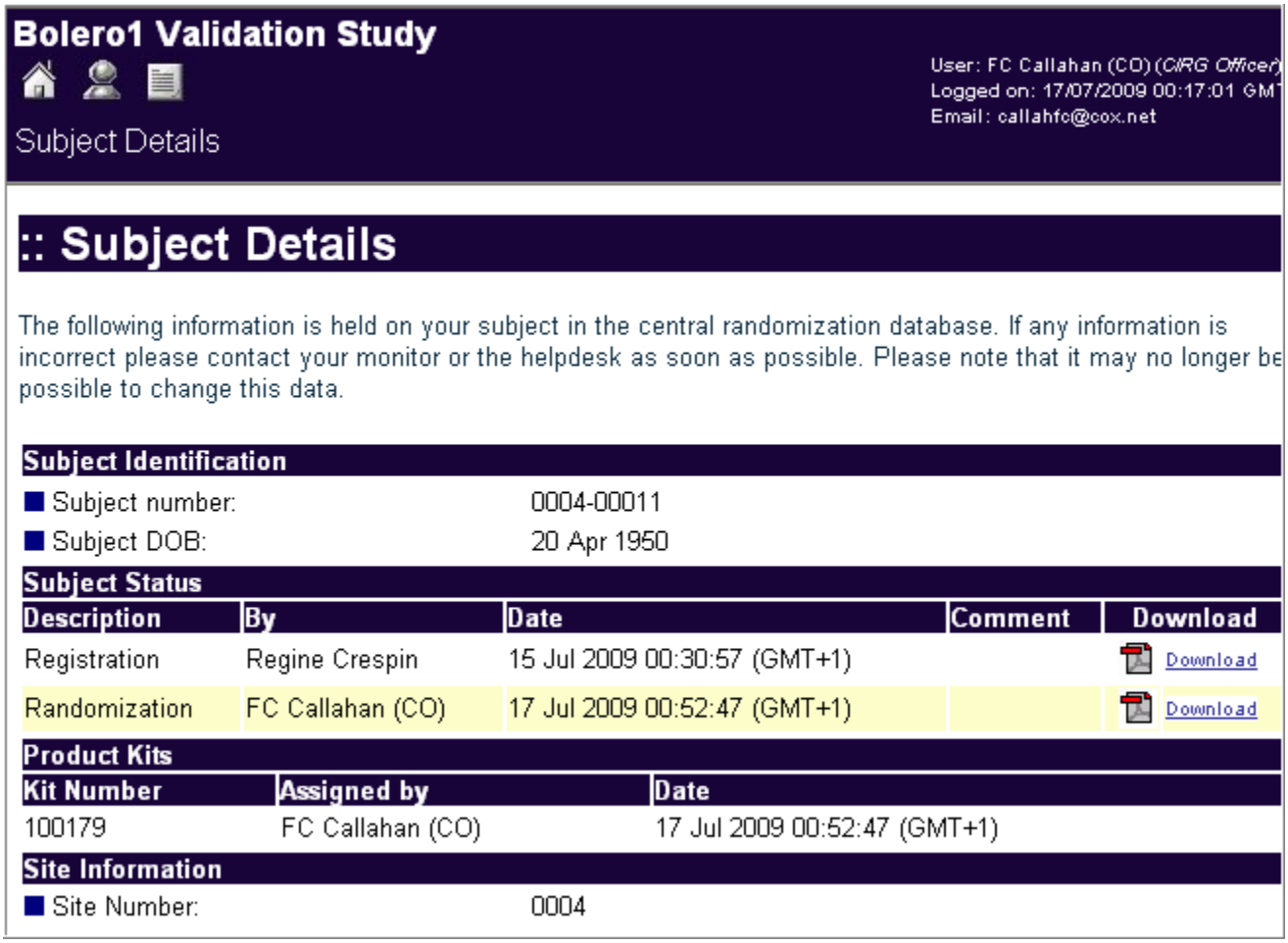
The Randomization Result screen.



9.5 Subject Details

The details of the randomization are presented on the subject's Subject Details screen. You may also view, print, or download the randomization confirmation document in PDF format by clicking the associated *Download* link. The medication kit allocated to the subject at randomization is listed in the *Product Kits* section of the page.

Subject Details after randomization.



Bolero1 Validation Study

User: FC Callahan (CO) (*CIRG Officer*)
Logged on: 17/07/2009 00:17:01 GMT
Email: callahfc@cox.net

Subject Details

:: Subject Details

The following information is held on your subject in the central randomization database. If any information is incorrect please contact your monitor or the helpdesk as soon as possible. Please note that it may no longer be possible to change this data.

Subject Identification

Subject number:	0004-00011
Subject DOB:	20 Apr 1950

Subject Status

Description	By	Date	Comment	Download
Registration	Regine Crespin	15 Jul 2009 00:30:57 (GMT+1)		Download
Randomization	FC Callahan (CO)	17 Jul 2009 00:52:47 (GMT+1)		Download

Product Kits

Kit Number	Assigned by	Date
100179	FC Callahan (CO)	17 Jul 2009 00:52:47 (GMT+1)

Site Information

Site Number:	0004

10 Medication Allocation

At each cycle for a subject, a medication kit is allocated to the subject in ID-net using the Medication Allocation feature. In order to prevent partial unblinding, at least one kit for each treatment arm must be On Site at your site to complete the allocation.

10.1 Interval Between Allocations

A minimum of 21 days is required between medication allocations. This interval is calculated with the previous allocation date being Day 0 and the next date at which an allocation may be requested as Day 22. For example, if the previous allocation date is 30 June, the first day the next allocation may be requested for the subject is 22 July.

If you attempt to perform the medication allocation transaction before the 21-day interval is complete, you will receive a message informing you of this.

You will see this message if the interval between allocation requests is less than 21 days.

Note that all dates in ID-net are calculated on the basis of Central European Time (GMT +1). Therefore, if you think the 21-day interval has passed but you do not have the allocation option, check your login time and date in ID-net. If it is close to midnight, the option may appear once the ID-net server time changes to the next day. You can refresh the time and date by pressing the F5 key on your keyboard. The IDDI Help Desk can also be contacted if you are still experiencing errors.

Your login date and time is displayed in the ID-net Title Bar.

It may be almost 08:00 on Thursday in eastern Australia, but it is still Wednesday for the ID-net server.

10.2 Completing the Medication Allocation Form

To allocate a medication kit for a subject, open the options for the subject in the tree view by clicking the '+' symbol next to the Subject ID, and then click the *Medication Allocation* link. This opens the allocation data-capture screen.

Complete the form, entering the requested information in each section.

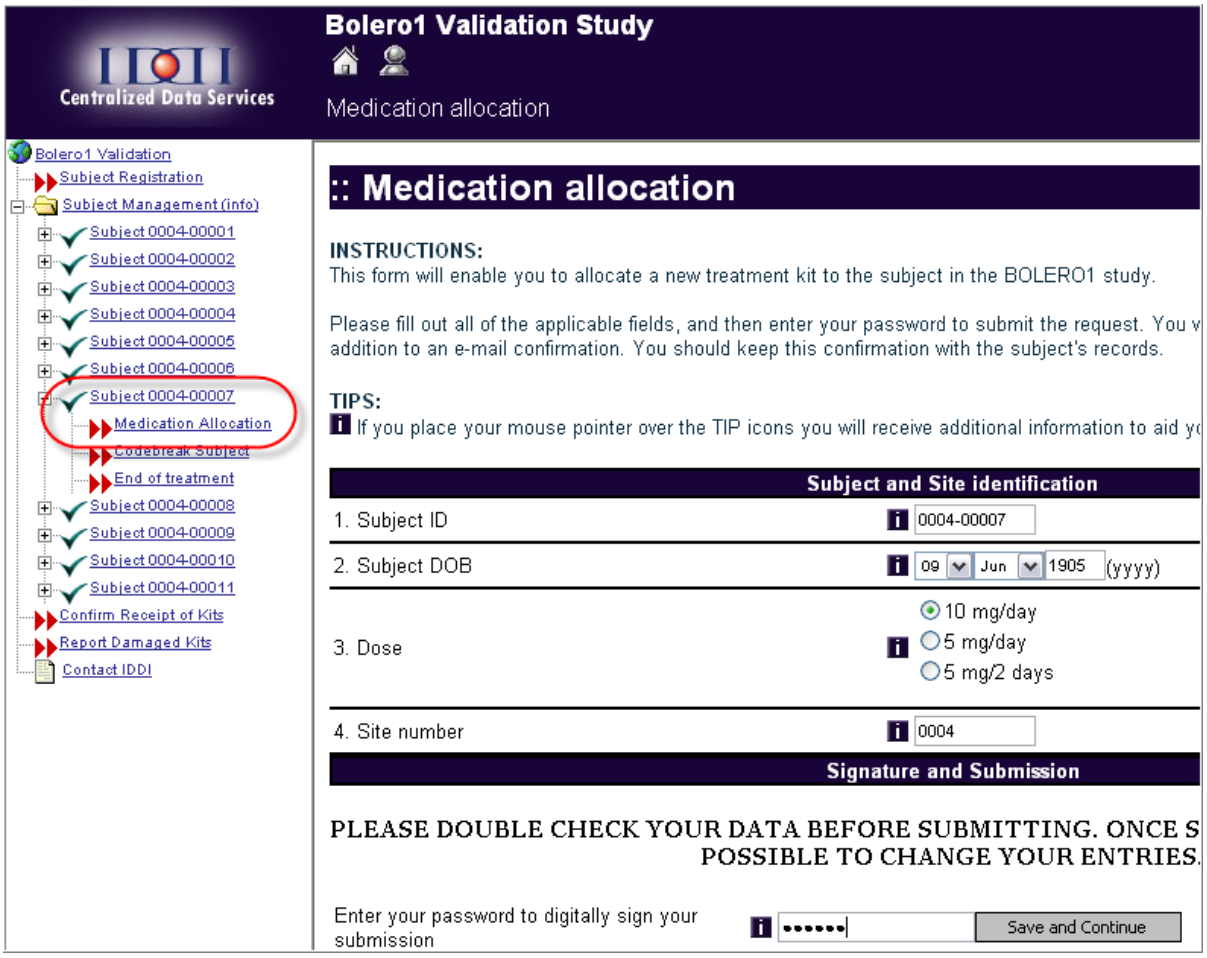
All questions must be answered to complete the medication allocation.

- **Subject ID:** pre-filled
- **Subject DOB:** Enter the date of birth
- **Dose:** Choose one of the three dose options
  - 10 mg/day
  - 5 mg/day
  - 5 mg/2 days
  - ***NOTE:*** *Once a dose lower than the initial dose is selected, it is not possible to return to a higher dose at any subsequent visit.*
- **Site Number:** This is pre-filled. If the site number is incorrect, cancel the allocation transaction and contact the IDDI Help Desk.

Once all information is entered, sign the form with your ID-net password and click the *Save and Continue* button.

Signing the Medication Allocation form.

The Medication Allocation form with all fields completed.



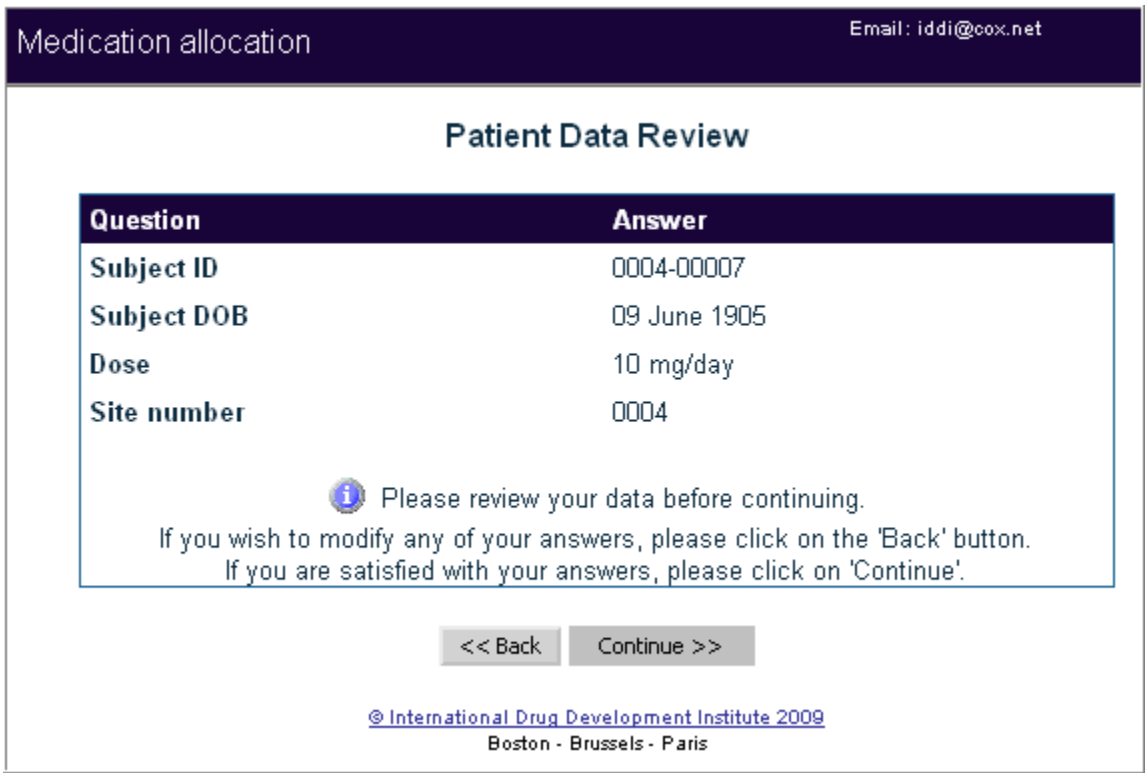
10.3 Medication Allocation Data Review

When you click the *Save and Continue* button on the Medication Allocation form, you will be presented with the Data Review screen. Here you may review the information entered for your subject. If any of the information is incorrect, click the *Back* button to return to the Medication Allocation form.

- **Please review this information carefully! Once a kit is allocated, it may not be possible to correct any errors.**

If all information is correct, click the *Continue* button to complete the allocation transaction.

The Medication Allocation Data Review screen.



10.4 Medication Allocation Result Screen

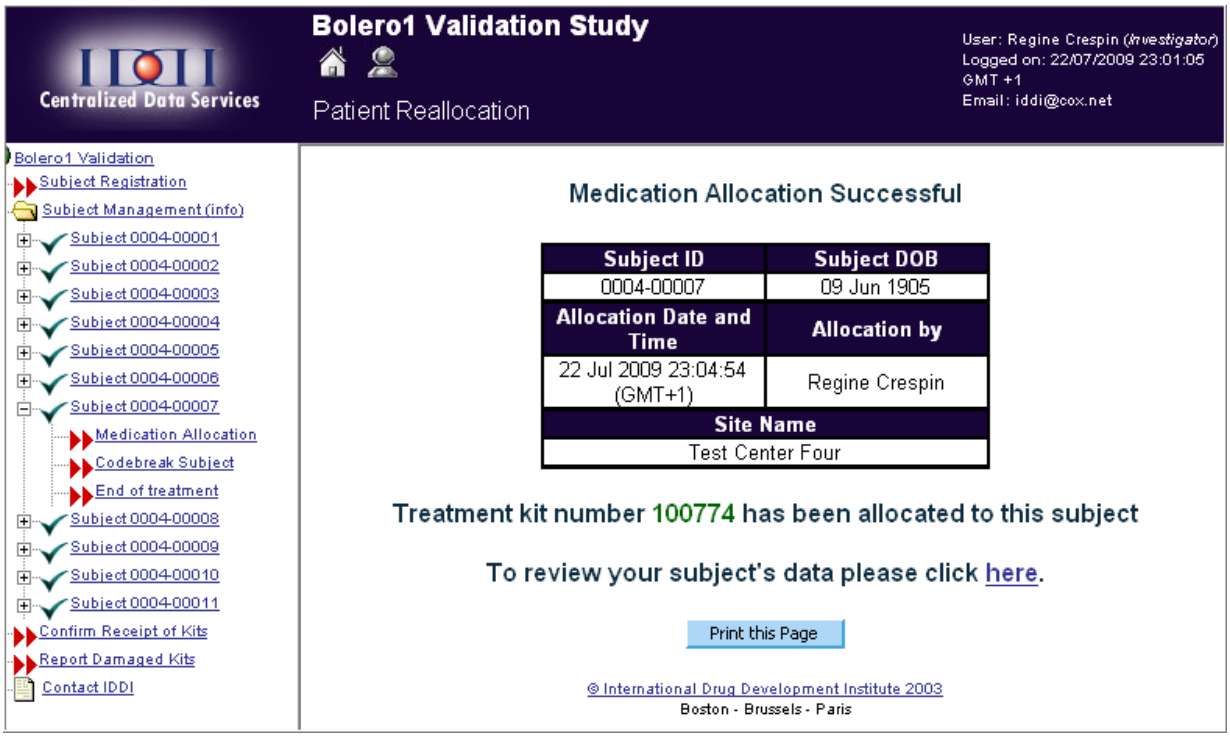
When you click the *Continue* button on the Data Review screen, the transaction is completed and you are presented with the Medication Allocation Result screen. On this screen you will see information related to the allocation, including the medication kit allocated to the subject, the date and time of the allocation, the individual who performed the allocation, and other relevant information. Note that all dates and times in ID-net are the local time in Belgium, where the IDDI servers are located.

You may print the Result screen for your records by clicking the *Print This Page* button. Please note that once you leave this screen, it is no longer available for viewing or printing. All designated users will receive a confirmation document in PDF format as an email attachment.

The following actions are available for the subject after medication allocation:

- Medication Allocation
- Code Break
- End of Treatment

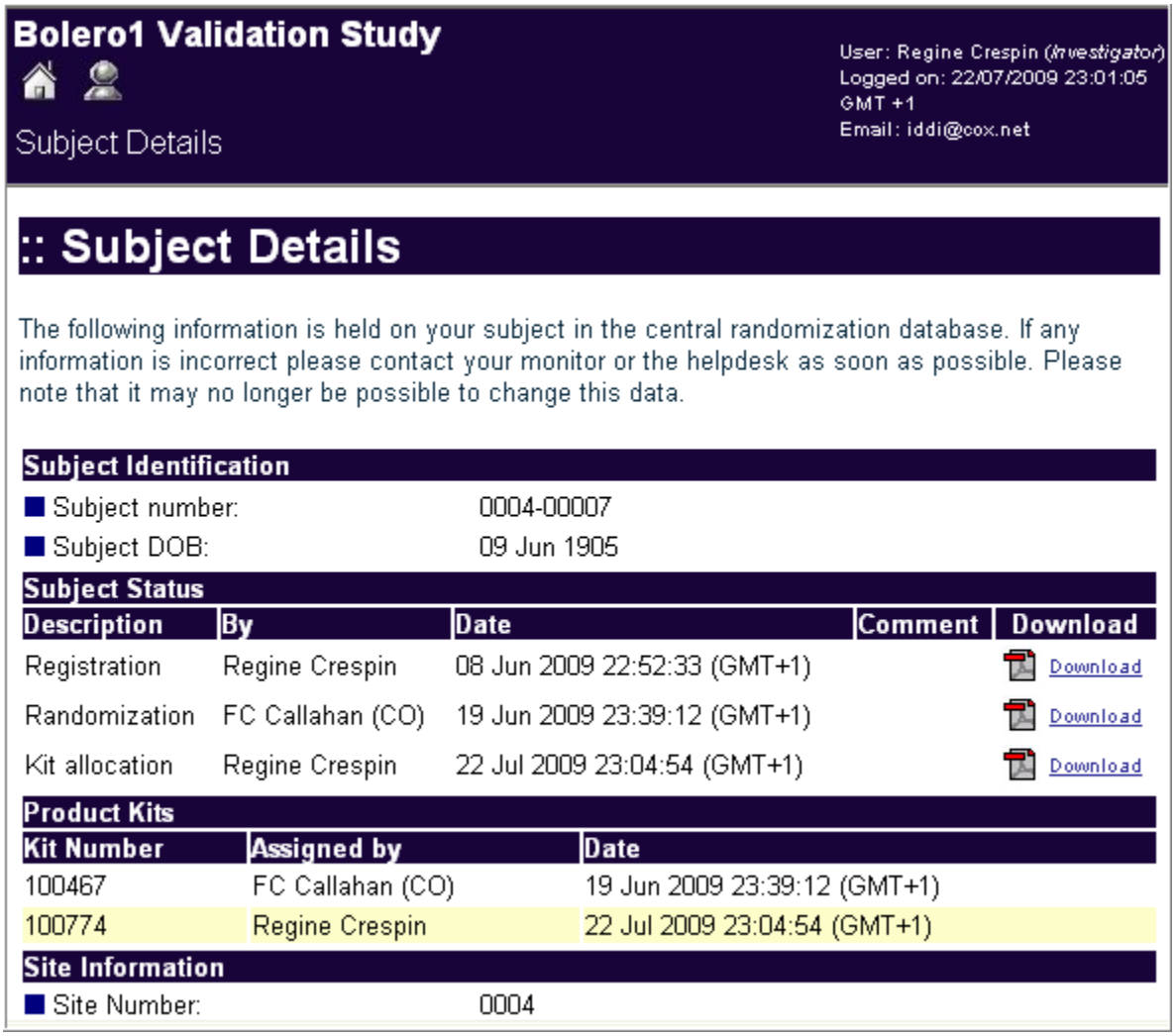
Medication Allocation Result screen.



10.5 Subject Details

The details of the allocation are presented on the subject's Subject Details screen. You may also view, print, or download the allocation confirmation document in PDF format by clicking the associated *Download* link. The medication kit allocated to the subject is listed in the *Product Kits* section of the page.

Subject Details after Medication Allocation.



11 Subject End of Treatment (everolimus)

A subject who leaves everolimus treatment should be reported as End of Treatment in ID-net. Once a subject is reported as End of Treatment, no further medication allocations are possible. The option for Code Break will remain available.

IMPORTANT: The End of Treatment in ID-net is different than the End of Treatment in the CRF. In ID-net this refers to the end of everolimus treatment.

11.1 Completing the End of Treatment Form

To report the end of randomized (everolimus) treatment for a subject, open the options for the subject in the tree view by clicking the '+' symbol next to the Subject ID, and then click the *End of Treatment* link. This opens the end of treatment data-capture screen.

Complete the form, entering the requested information in each section.

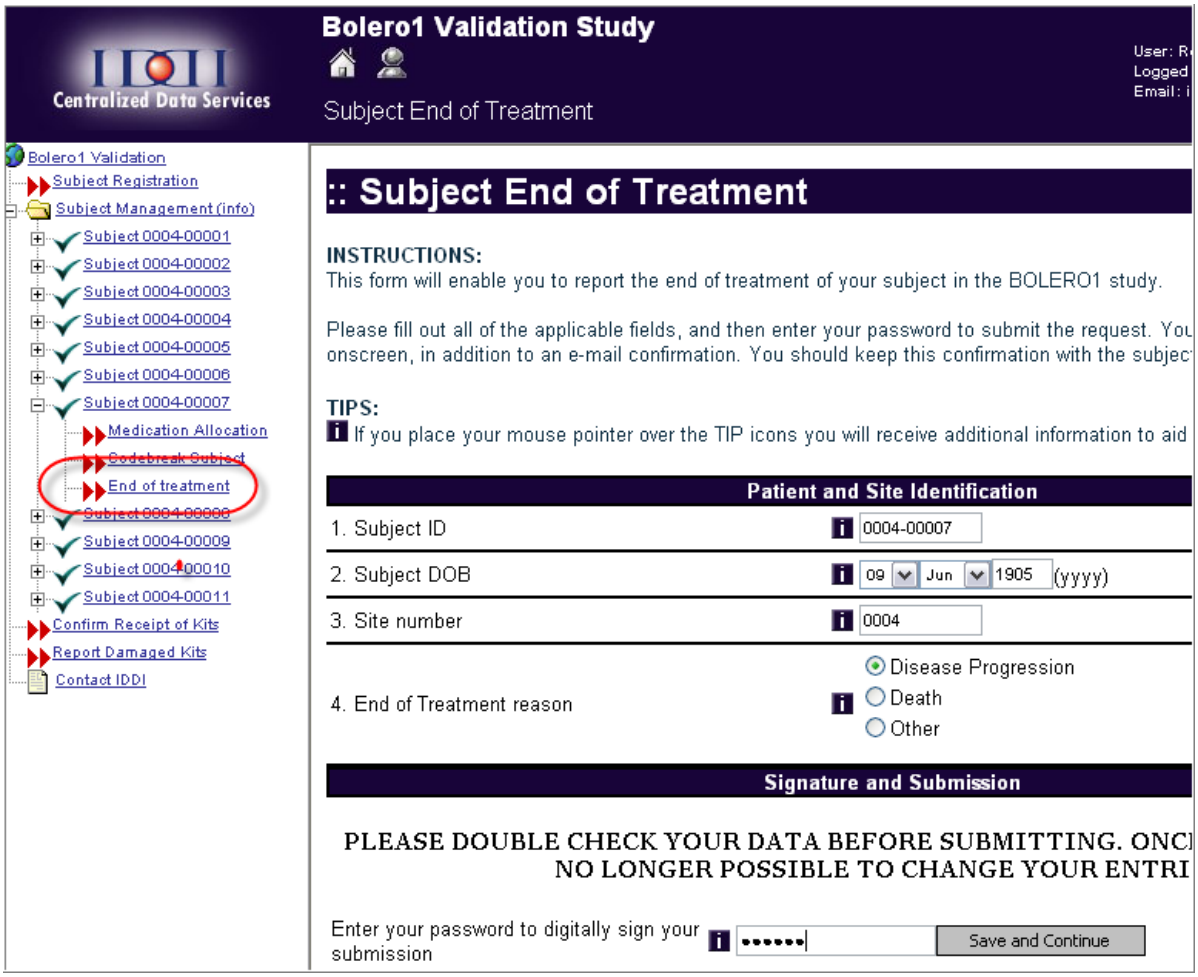
All questions must be answered to complete the randomization.

- **Subject ID:** pre-filled
- **Subject DOB:** Enter the date of birth recorded at the time of registration.
- **End of Treatment Reason:** Choose one of the three options:
  - Disease Progression
  - Death
  - Other
- **Site Number:** This is pre-filled. If the site number is incorrect, cancel the End of Treatment transaction and contact the IDDI Help Desk.

Once all information is entered, sign the form with your ID-net password and click the *Save and Continue* button.

Signing the End of Treatment form.

The End of Treatment form with all fields completed.



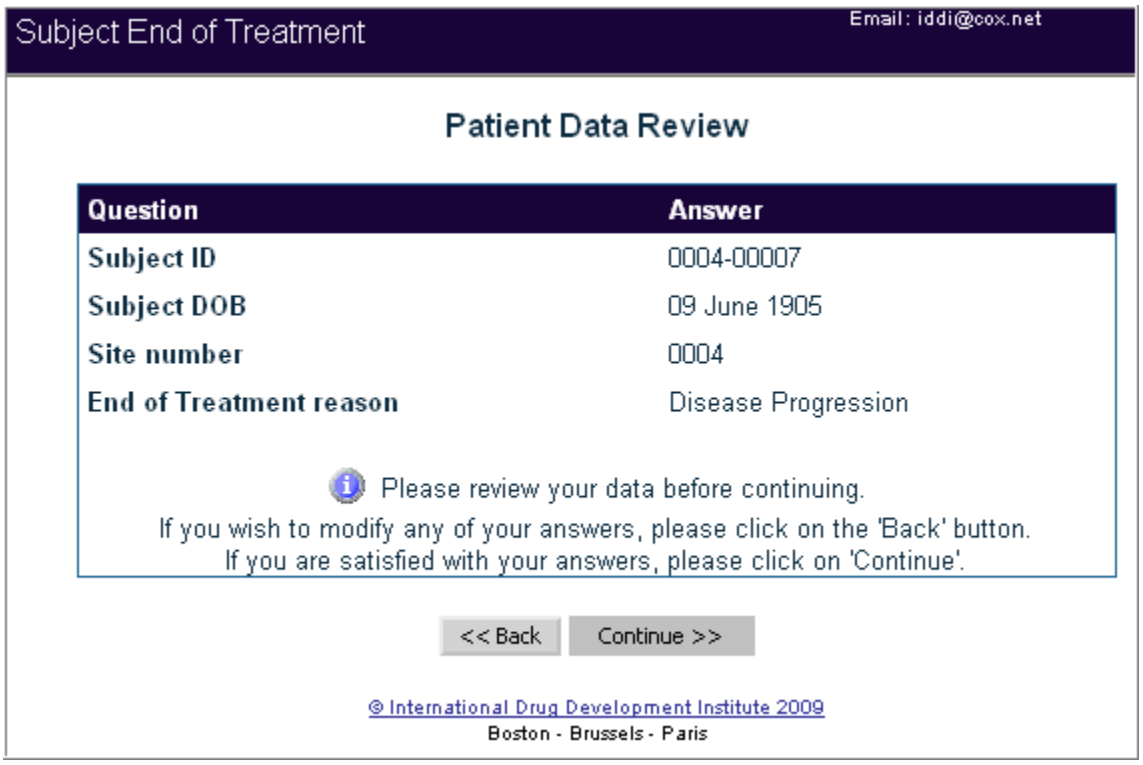
11.2 End of Treatment Data Review

When you click the *Save and Continue* button on the End of Treatment form, you will be presented with the Data Review screen. Here you may review the information entered for your subject. If any of the information is incorrect, click the *Back* button to return to the End of Treatment form.

- **Please be certain you want to perform this transaction. A subject reported as End of Treatment is withdrawn from the study in ID-net.**

If all information is correct, click the *Continue* button to complete the allocation transaction.

The End of Treatment Data Review screen.



11.3 End of Treatment Result Screen

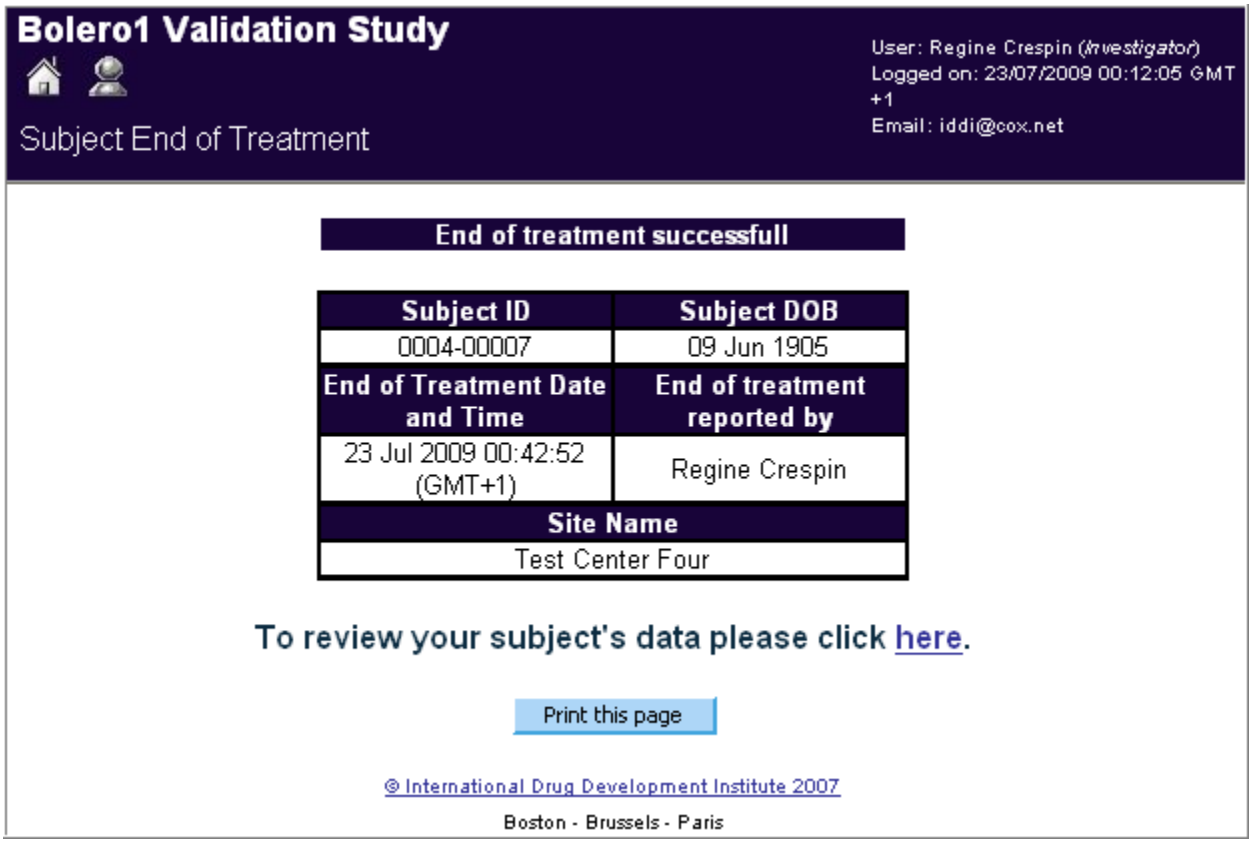
When you click the *Continue* button on the Data Review screen, the transaction is completed and you are presented with the End of Treatment Result screen. On this screen you will see information related to the transaction, including the date and time of the transaction, the individual who reported the end of treatment, and other relevant information. Note that all dates and times in ID-net are the local time in Belgium, where the IDDI servers are located.

You may print the Result screen for your records by clicking the *Print This Page* button. Please note that once you leave this screen, it is no longer available for viewing or printing. All designated users will receive a confirmation document in PDF format as an email attachment.

The following actions are available for the subject after being reported as end of treatment:

- Code Break

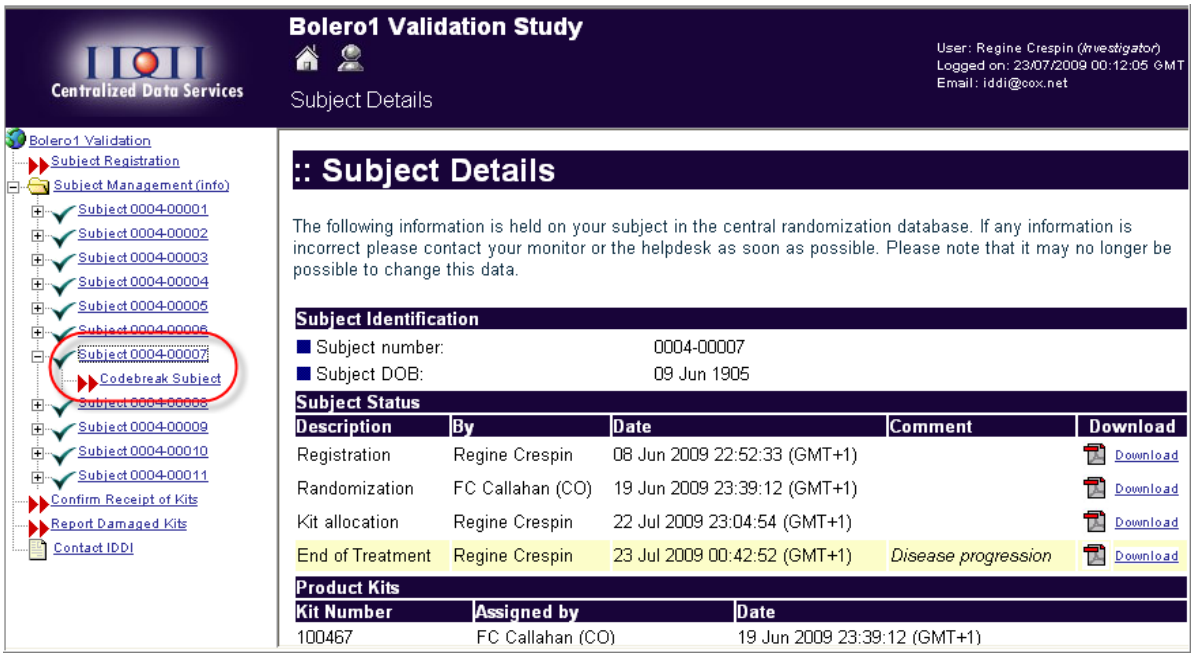
The Subject End of Treatment Result screen.



11.4 Subject Details

The details of the end of randomized treatment are presented on the subject's Subject Details screen. You may also view, print, or download the end-of-treatment confirmation document in PDF format by clicking the associated *Download* link.

Subject Details after subject is reported as End of Treatment. Note that only Code Break is available for the subject.



12 Subject Code Break

In rare cases were a subject's treatment needs to be revealed for reasons of safety, the Code Break function may be used. This function is available to users with Investigator or Safety Officer accounts in ID-net. Only the person performing the code break will receive the result. Please remember that this information will unblind you to the data.

Code break is available for all randomized subjects, including those who have been reported as end of treatment.

- **INVESTIGATORS SHOULD CONTACT NOVARTIS OR CIRG BEFORE PERFORMING A CODE BREAK.**

12.1 Completing the Code Break Form

To perform a code break for a subject, open the options for the subject in the tree view by clicking the '+' symbol next to the Subject ID, and then click the *Code Break Subject* link. This opens the code break data-capture screen. Safety Officers should select the subject's site from the drop-down list to locate the subject's record.

Complete the form, entering the requested information in each section.

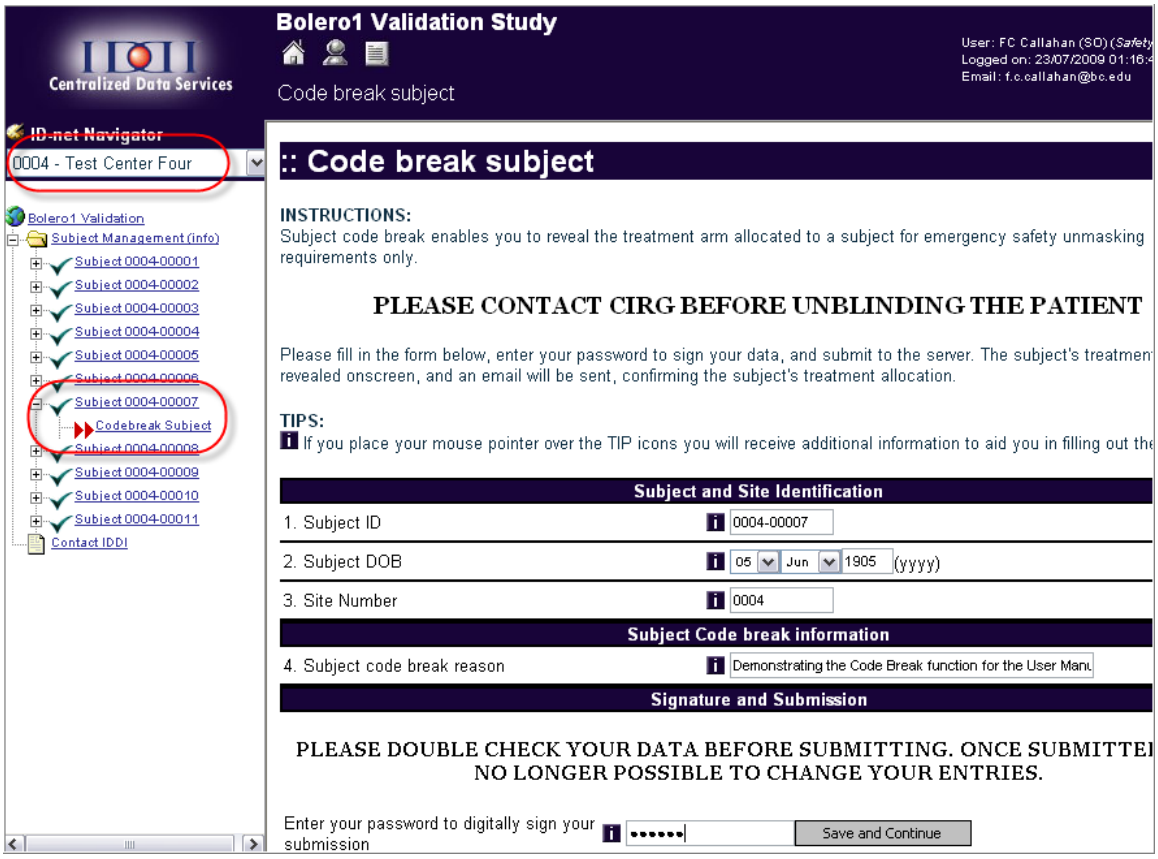
All questions must be answered to complete the code break transaction.

- **Subject ID:** pre-filled
- **Subject DOB:** Enter the date of birth recorded at the time of registration.
- **Site Number:** This is pre-filled. If the site number is incorrect, cancel the code break transaction and contact the IDDI Help Desk.
- **Subject Code Break Reason:** Enter the reason for the code break in the text box. This field accepts up to 100 alpha-numeric characters.

Once all information is entered, sign the form with your ID-net password and click the *Save and Continue* button.

Signing the Subject Code Break form.

The Code Break form with all fields completed (Safety Officer profile).

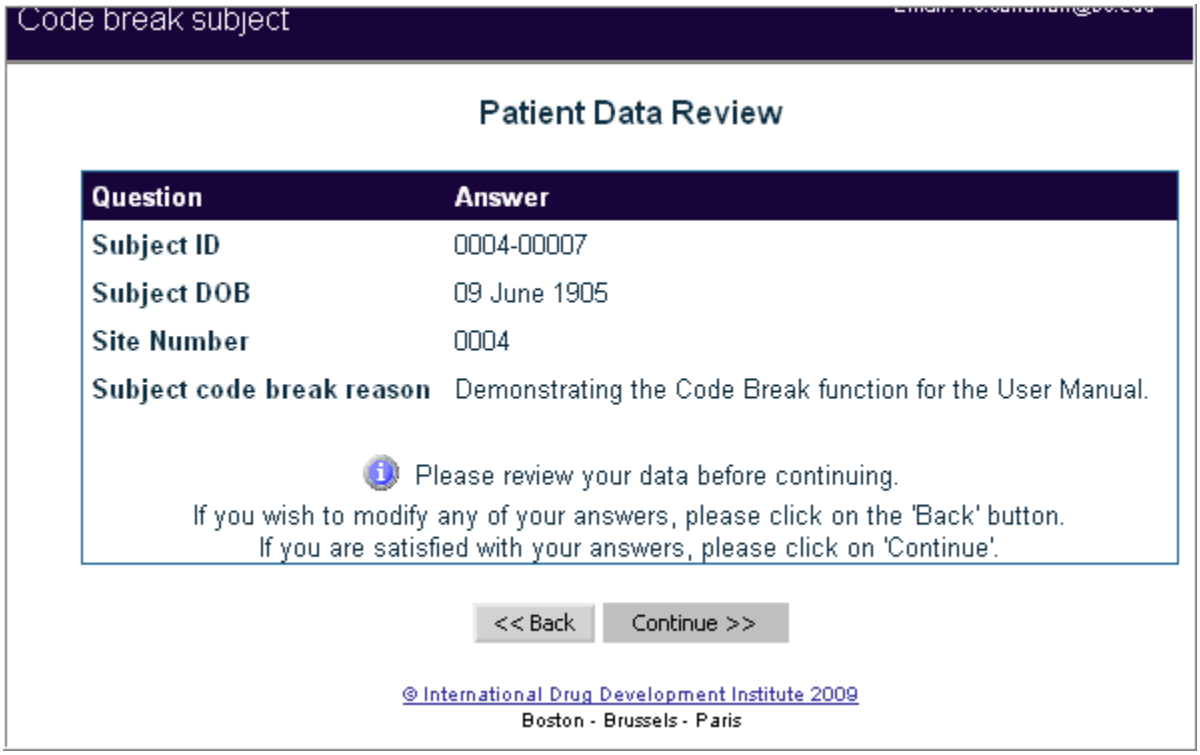


12.2 Code Break Data Review

When you click the *Save and Continue* button on the Code Break form, you will be presented with the Data Review screen. Here you may review the information entered for your subject. If any of the information is incorrect, click the *Back* button to return to the Code Break form.

If all information is correct, click the *Continue* button to complete the code break transaction.

The Code Break Data Review screen.



12.3 Code Break Result Screen

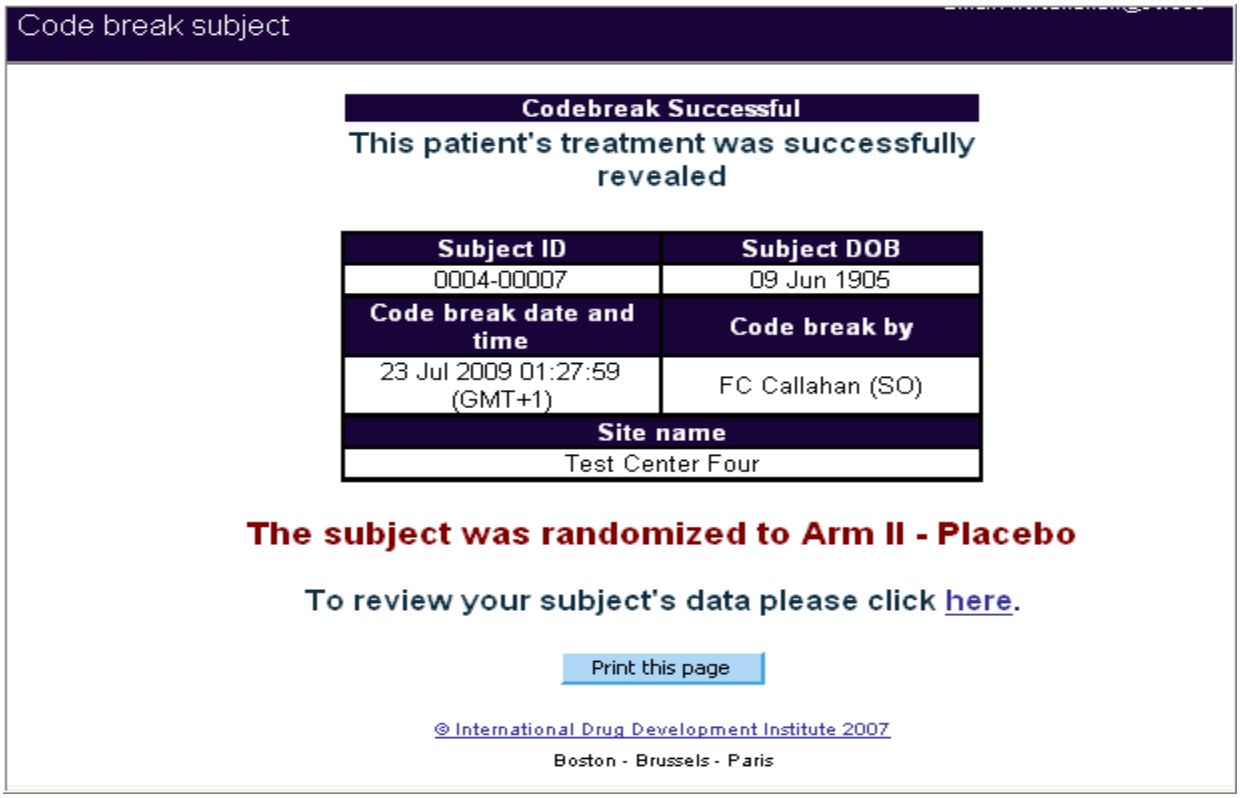
When you click the *Continue* button on the Data Review screen, the transaction is completed and you are presented with the Code Break Result screen. On this screen you will see information related to the transaction, including the subject's treatment, the date and time of the transaction, the individual who performed the code break and other relevant information. Note that all dates and times in ID-net are the local time in Belgium, where the IDDI servers are located.

You may print the Result screen for your records by clicking the *Print This Page* button. Please note that once you leave this screen, it is no longer available for viewing or printing. In addition, for code breaks no PDF will be available for downloading.

The following actions are available for the subject after a code break:

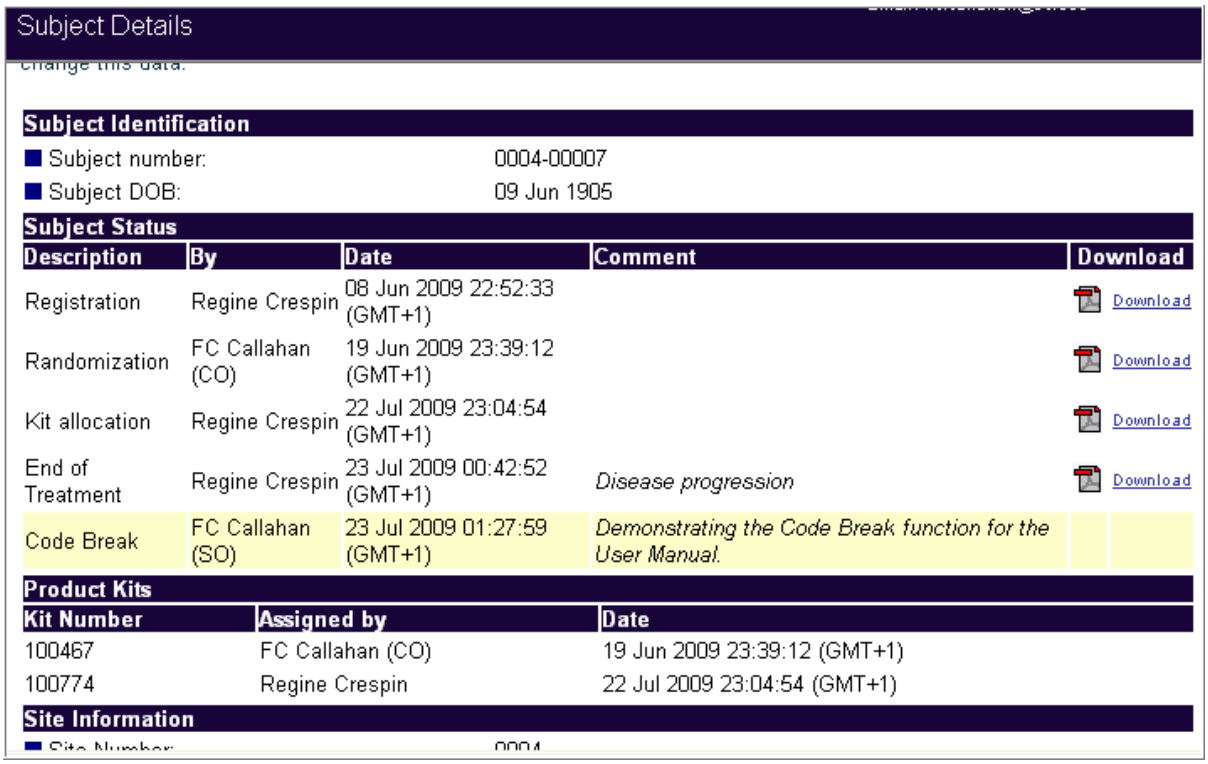
- Code Break
- Medication Allocation (for subjects not reported as end of treatment)

The Subject Code Break Result screen.



12.4 Subject Details

The reason for code break is listed in the subject's Subject Details screen, but not the subject's treatment. No confirmation document is available for download for code breaks.



Subject Details

change this data.

Subject Identification

- Subject number: 0004-00007
- Subject DOB: 09 Jun 1905

Subject Status

Description	By	Date	Comment	Download
Registration	Regine Crespin	08 Jun 2009 22:52:33 (GMT+1)		Download
Randomization	FC Callahan (CO)	19 Jun 2009 23:39:12 (GMT+1)		Download
Kit allocation	Regine Crespin	22 Jul 2009 23:04:54 (GMT+1)		Download
End of Treatment	Regine Crespin	23 Jul 2009 00:42:52 (GMT+1)	*Disease progression*	Download
Code Break	FC Callahan (SO)	23 Jul 2009 01:27:59 (GMT+1)	*Demonstrating the Code Break function for the User Manual.*	

Product Kits

Kit Number	Assigned by	Date
100467	FC Callahan (CO)	19 Jun 2009 23:39:12 (GMT+1)
100774	Regine Crespin	22 Jul 2009 23:04:54 (GMT+1)

Site Information

- Site Number: 0004

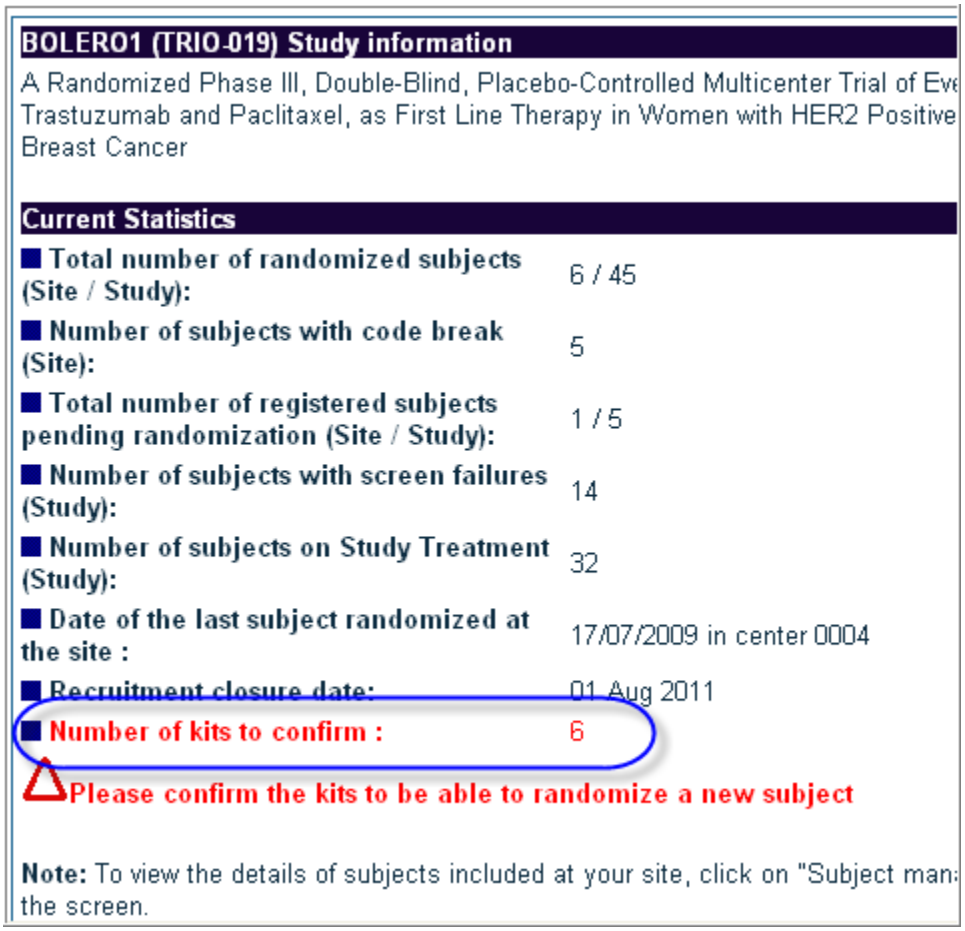
13 Medication Management

The supply of study drug is managed by ID-net. Site-level users (Investigators, Study Coordinators, and Pharmacists) only have the capability of confirming receipt of supply shipments and reporting medication kits as damaged. The initial shipment (6 kits) will be sent to the site when the first subject is registered in ID-net, and re-supply will be automatic.

13.1 Confirm Receipt of Medication

If a medication shipment is In Transit to your site, the quantity of kits in the shipment is displayed on your ID-net home page. These kits must be confirmed as received in ID-net before they are available for allocation to subjects. Confirmation should be performed immediately, because not confirming receipt of medication may prevent the randomization of new subjects at your site or the shipment of re-supply kits.

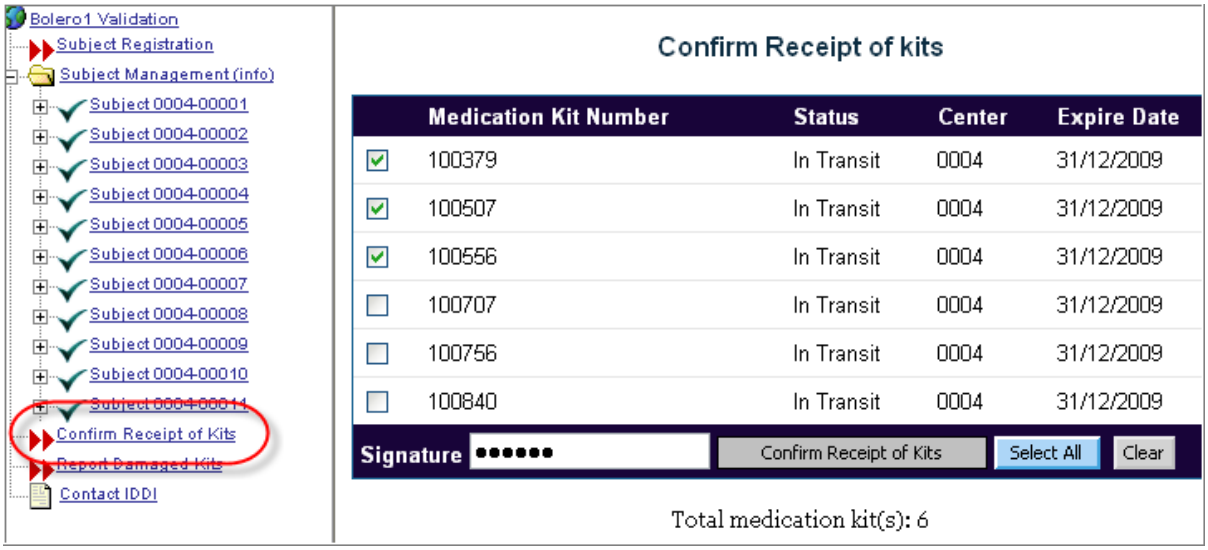
This site has six kits In Transit that need to be confirmed as received.



To confirm receipt of medication, click on the *Confirm Receipt of Kits* link in the tree view. This opens the Confirm Receipt of Kits screen. Here you will see a list of all kits In Transit to your site. Check the box next to each kit you have received, sign the form with your ID-net password, and click the *Confirm Receipt of Kits* button. Please note that the button does not become active until you have checked at least one check box.

- **Be sure to select only those kits you have actually received, otherwise ID-net may allocate to a subject a kit you do not have On Site.**

The Confirm Receipt of Kits screen.

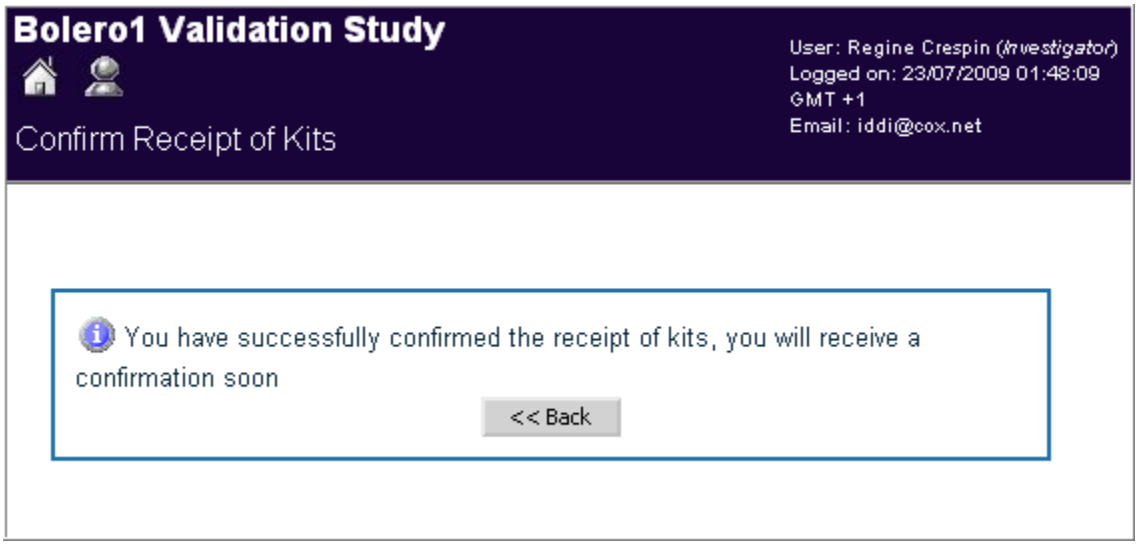


If you are certain you have received all the kits in the list, you may use the *Select All* button to select them all at once. When you click the *Confirm Receipt of Kits* button, the selected kits are moved from "In Transit" to "On Site" status and are available for allocation to subjects. A Result screen appears, confirming the success of the transaction. Clicking the *Back* button on this screen returns you to the Confirm Receipt of Kits screen.

A confirmation document in PDF format is sent to all designated users as an email attachment.

Signing the Confirm Receipt of Kits form.

The Confirm Receipt of Kits Result screen.



13.2 Report Damaged Kits

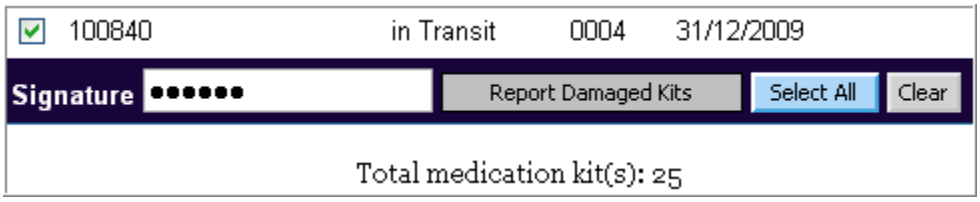
If a medication is found to be damaged, you should report it damaged in ID-net using the Report Damaged Kits function. Any kit that is In Transit, On Site, or that has been allocated to a subject may be reported as damaged.

- **In cases where the damaged kit has already been allocated but not used by the subject, the kit will be disassociated from the subject in ID-net. The site will need to call the IDDI Help Desk for a replacement kit.** Since this requires a manual update to the database, ID-net will not show the change until the next business day in Belgium.

- **Kits already used must not be reported as damaged.**

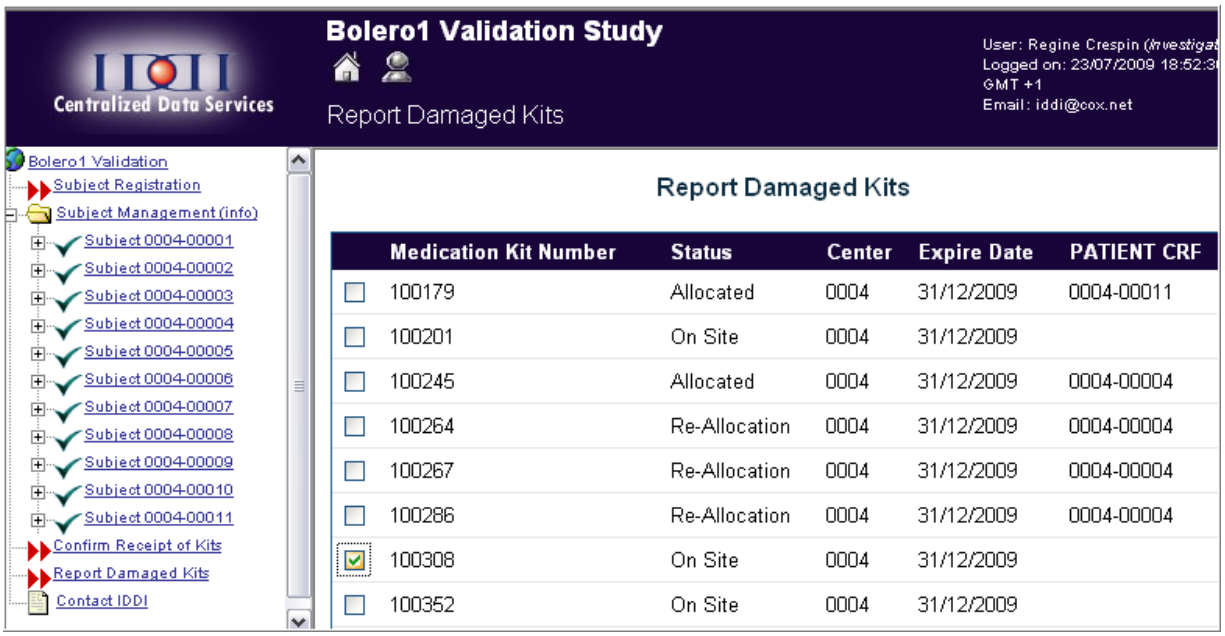
To report a kit as damaged, click on the *Report Damaged Kits* link in the tree view. This opens the Report Damaged Kits screen. Here you will see a list of all kits that have been shipped to your site, excluding blocked, damaged, and expired kits. Check the box next to each kit you need to report as damaged, sign the form with your ID-net password, and click the *Report Damaged Kits* button. Please note that the button does not become active until you have checked at least one check box.

Signing the Report Damaged Kits form.



Although it is an option, we recommend that you do **not** use the *Select All* button due to the risk of reporting kits as damaged that are not in fact damaged—especially kits already allocated to subjects.

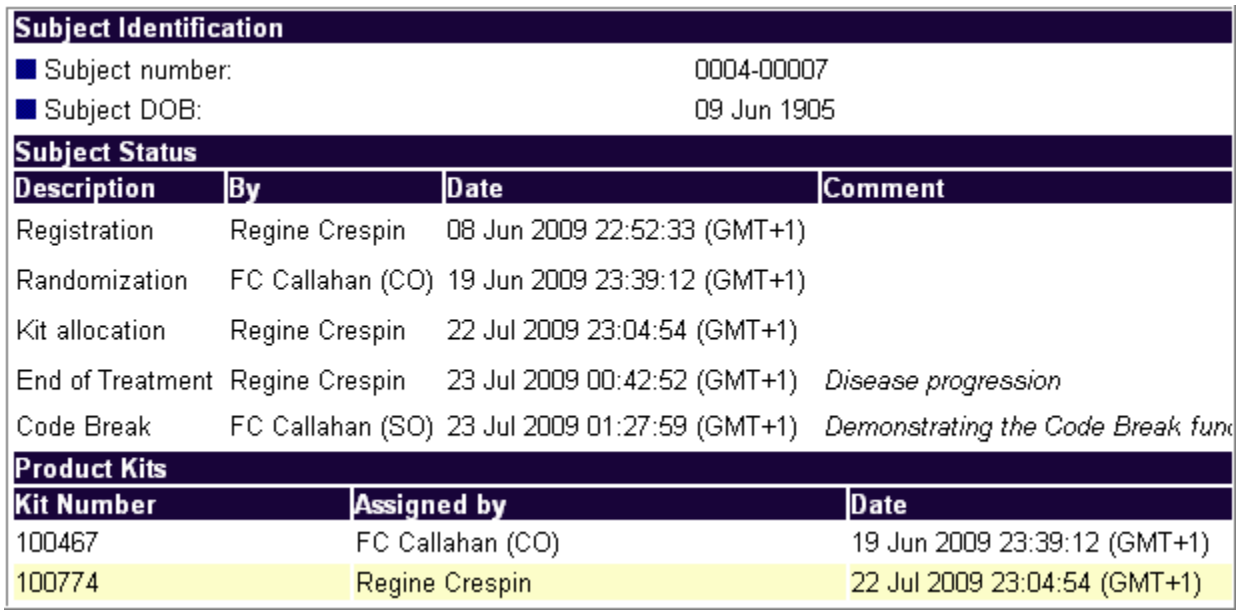
The Report Damaged Kits screen.



Once you are certain the correct kits have been selected, sign the form with your ID-net password and click the *Report Damaged Kits* button to complete the transaction. You will be presented with a Result screen indicating that the transaction was successful. Clicking the *Back* button on this screen returns you to the Report Damaged Kits screen.

If the kit reported as damaged has already been allocated to a subject but not used, it is removed from the subject's record and no longer appears on the subject's Subject Details screen. If the kit was In Transit, it no longer appears in the list of kits on the Confirm Receipt of Kits screen.

Kit 100774 has been allocated to Subject 0004-00007.



Subject Identification

- Subject number: 0004-00007
- Subject DOB: 09 Jun 1905

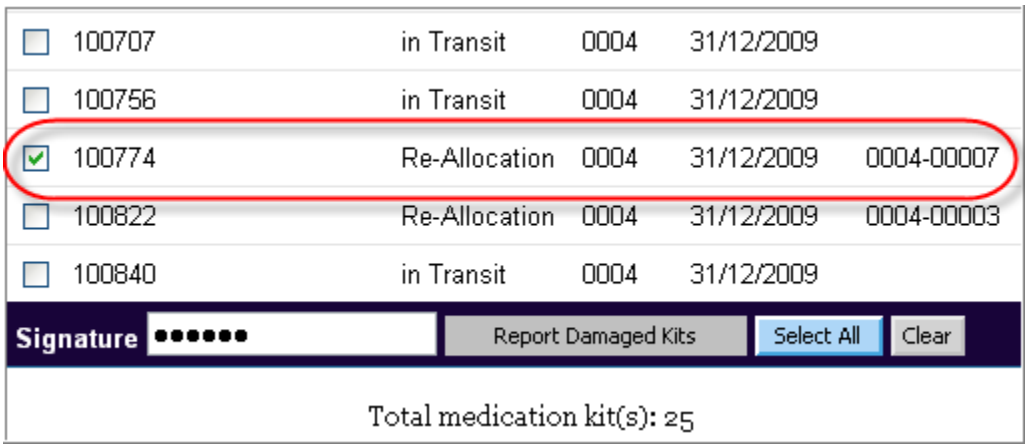
Subject Status

Description	By	Date	Comment
Registration	Regine Crespin	08 Jun 2009 22:52:33 (GMT+1)	
Randomization	FC Callahan (CO)	19 Jun 2009 23:39:12 (GMT+1)	
Kit allocation	Regine Crespin	22 Jul 2009 23:04:54 (GMT+1)	
End of Treatment	Regine Crespin	23 Jul 2009 00:42:52 (GMT+1)	*Disease progression*
Code Break	FC Callahan (SO)	23 Jul 2009 01:27:59 (GMT+1)	*Demonstrating the Code Break fun*

Product Kits

Kit Number	Assigned by	Date
100467	FC Callahan (CO)	19 Jun 2009 23:39:12 (GMT+1)
100774	Regine Crespin	22 Jul 2009 23:04:54 (GMT+1)

Reporting Kit 100774 as damaged.

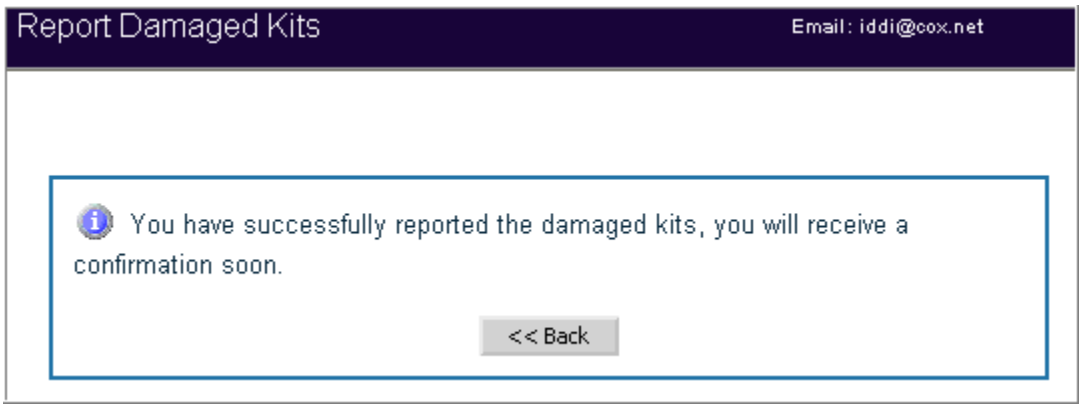


☐	100707	in Transit	0004	31/12/2009	
☐	100756	in Transit	0004	31/12/2009	
☑	100774	Re-Allocation	0004	31/12/2009	0004-00007
☐	100822	Re-Allocation	0004	31/12/2009	0004-00003
☐	100840	in Transit	0004	31/12/2009	

Signature ●●●●●● Report Damaged Kits Select All Clear

Total medication kit(s): 25

The Report Damaged Kits Result screen.



Kit 100774 is no longer associated with the subject.

Subject Identification

Subject number:	0004-00007
Subject DOB:	09 Jun 1905

Subject Status

Description	By	Date	Comment
Registration	Regine Crespin	08 Jun 2009 22:52:33 (GMT+1)	
Randomization	FC Callahan (CO)	19 Jun 2009 23:39:12 (GMT+1)	
Kit allocation	Regine Crespin	22 Jul 2009 23:04:54 (GMT+1)	
End of Treatment	Regine Crespin	23 Jul 2009 00:42:52 (GMT+1)	*Disease progression*
Code Break	FC Callahan (SO)	23 Jul 2009 01:27:59 (GMT+1)	*Demonstrating the Code Break func*

Product Kits

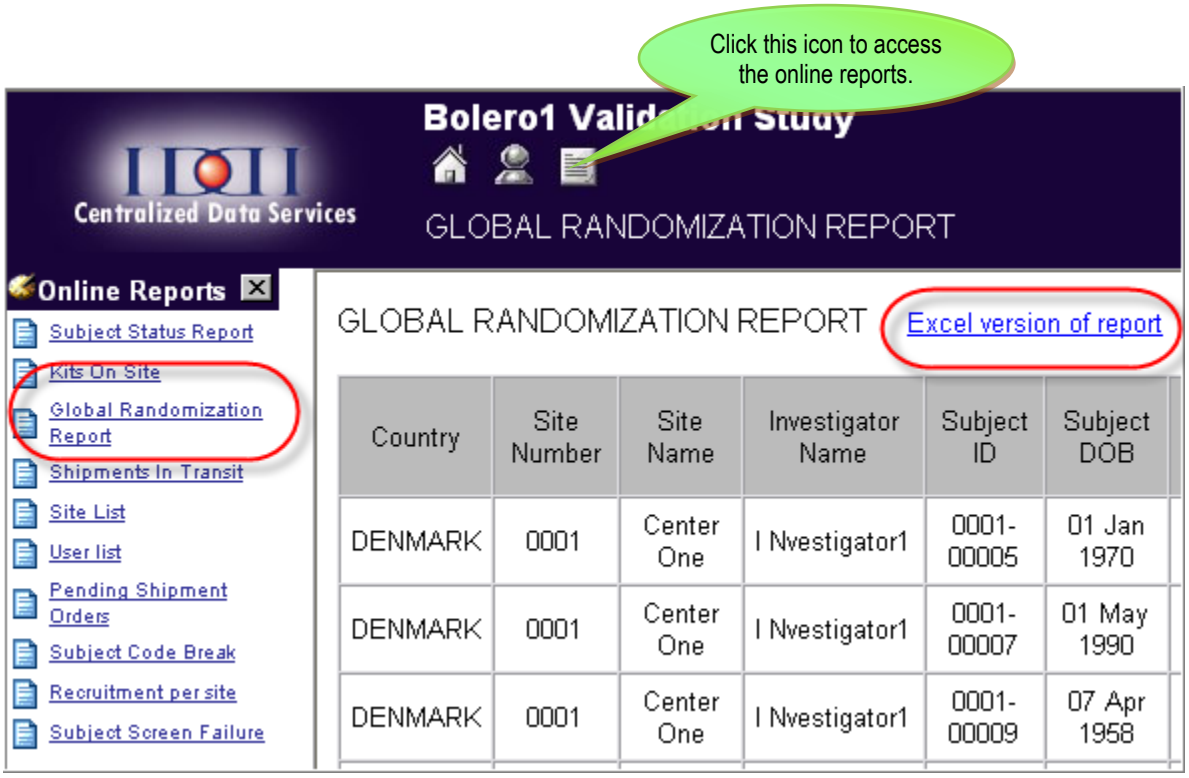
Kit Number	Assigned by	Date
100467	FC Callahan (CO)	19 Jun 2009 23:39:12 (GMT+1)

Site Information

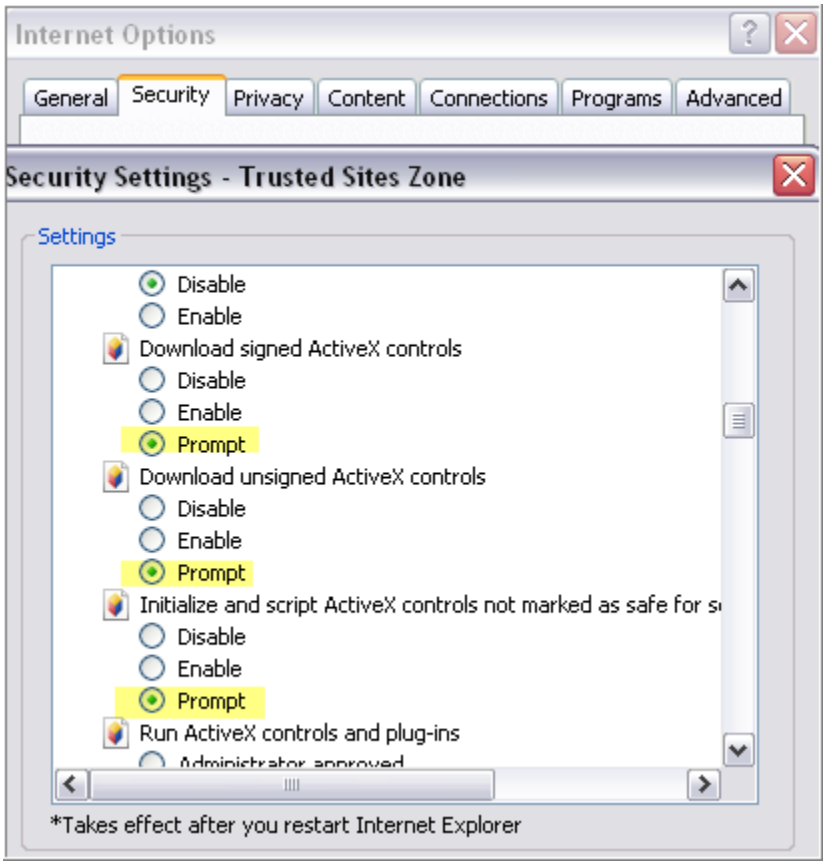
Site Number:	0004
Site Name:	Test Center Four

14 Reports

The Reports section of ID-net is available to Sponsors, CIRG Officers, Monitors, and Drug Distributors. In this section, a variety of online reports are available, depending on the user's profile. These reports are accessed by clicking the *Online Reports* icon in the title bar of your Home Page. Some reports may be opened and saved as Excel® worksheets.



It may be necessary to change certain Internet Explorer security settings regarding ActiveX controls in order to open the reports as Excel files. Your site's IT specialist can show you how to do this.



To return to your home page and access Subject Management (info), click the *Open Navigator* icon:

15 Help Desk

For routine support queries or requests, please send an email message to the IDDI Help Desk at helpdesk@iddi.com.

For urgent issues, IDDI provides 24/7 telephone support:

- Europe: +32 16 270 969.
  The operator will ask the caller his name, the study protocol number, the sponsor, the site number, the phone number, the fax number, and description of the problem.

For issues arising during North American business hours, you may call the U.S.-based Help Desk at +1-866-767-4334. This number is available 24/7.

This contact information is also available by clicking the *Contact IDDI* link in the Navigator pane.

16 Site Staffing Changes

All requests for new user access must be approved by the sponsor, so please forward all requests for new user accounts to your monitor.

It is important that all information in ID-net regarding site personnel be current at all times. All changes in site personnel or in the names or contact information of study participants, must also be approved by the sponsor. Therefore, please direct all such requests to your monitor.